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THE HOLISTIC ASSESSMENT AND CARE PLANNING IN PARTNERSHIP (HAPPI) STUDY A MIXED METHODS FEASIBILITY STUDY OF A NURSE-LED INTERVENTION FOR OLDER PEOPLE WHO LIVE WITH FRAILITY

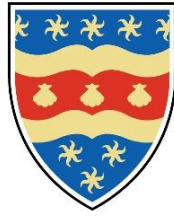
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UNIVERSITY OF PLYMOUTH

THE HOLISTIC ASSESSMENT AND CARE PLANNING IN PARTNERSHIP

(HAPPI) STUDY

A MIXED METHODS FEASIBILITY STUDY OF A NURSE-LED INTERVENTION

FOR OLDER PEOPLE WHO LIVE WITH FRAILTY

by

HELEN ANNE LYNDON

A thesis submitted to the University of Plymouth
in partial fulfilment for the degree of

DOCTOR OF PHILOSOPHY

School of Nursing and Midwifery

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Copyright Statement

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Author's Declaration

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral College Quality Sub-Committee. Work submitted for this research degree at the University of Plymouth has not formed part of any other degree either at the University of Plymouth or at another establishment.

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Abstract

THE HOLISTIC ASSESSMENT AND CARE PLANNING IN PARTNERSHIP (HAPPI) STUDY

HELEN LYNDON

Aim

This mixed-methods feasibility study aimed to identify and to develop consensus on the components of a holistic assessment and care planning intervention for frail older people in primary care and to conduct a feasibility cluster randomised, controlled trial with an embedded qualitative study to assess potential trial methods for a definitive trial.

Background

Frailty is a serious but not inevitable consequence of ageing that can be managed as a long-term condition. Frail older people are more at risk to adverse health outcomes than the non-frail, yet many do not receive evidence based management including a comprehensive geriatric assessment (CGA); a holistic assessment and care planning approach. This is because the impact of CGA is well evidenced in a hospital setting, but less so with community-dwelling frail older people who receive the majority of their healthcare and support in primary care. It is not clear if this approach can be successfully delivered in primary care and whether a holistic assessment and care planning intervention can be led by nurses rather than the traditional geriatrician-led model.

Methods

Firstly, a patient and public involvement consultation informed the design of this mixed-methods feasibility study. Then a three-round e-Delphi study was carried out to gain consensus on the content of the intervention. A multi-site, feasibility, cluster randomised controlled trial (fRCT) with embedded qualitative study was conducted.

Findings

The e-Delphi survey provided consensus on the important and feasible components of the intervention. This was then further refined by research stakeholders to produce the Holistic Assessment and care Planning Intervention (HAPPI) assessment pack to be used in the fRCT. The fRCT demonstrated that it was possible to conduct a randomised controlled trial of the intervention in primary care, all feasibility criteria relating to recruitment and retention were achieved, outcome measures evaluated, and recommendations made for a definitive trial. The qualitative study determined that the intervention was acceptable to participants and judged as feasible to deliver by the nurses. Trial processes and procedures were feasible with some changes.

Conclusions

The study adds new knowledge having developed a nurse-led intervention for older people with frailty that can be delivered in primary care. It has demonstrated that the intervention is feasible and provided information to inform the conduct of the definitive randomised controlled trial.

Research outputs

Publications related to the work within this thesis are listed below:

Lyndon, H., Latour, J.M., Marsden, J., Campbell, S., Stevens, K., Kent, B. (2019).

The holistic assessment and care planning in partnership intervention study (HAPPI):

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Lyndon, H., Underwood, F., Latour, J.M., Marsden, J., Brown, A., Kent, B. (2020)

Effectiveness of nurse-coordinated, person-centred comprehensive assessment on improving quality of life of community-dwelling, frail older people: a systematic review protocol. *Joanna Briggs Institute Evidence Synthesis*. 18 (4), pp 824–831. doi: 10.11124/JBISRIR-D-19-00082.

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- University of Plymouth Postgraduate Research Showcase, January 2018, Plymouth
- University of Plymouth Clinical Schools Annual Conference, April 2018, Plymouth
- Cornwall Clinical Schools Annual Research Conference, May 2019, Cornwall

- British Gerontological Society Annual Conference, July 2019, Liverpool
- Cornwall Foundation NHS Trust Research Showcase, October 2018, Cornwall
- British Geriatrics Society Autumn Conference, October 2019, Leicester
- British Geriatrics Society South West Region Conference, October 2019, Exeter
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Lyndon, H. Designing a Nurse-Led Holistic Assessment and care Planning Intervention (HAPPI) to support Frail Older People in Primary Care.

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List of abbreviations

AE	Adverse Event
BGS	British Geriatrics Society
BI	Barthel Index
CGA	Comprehensive Geriatric Assessment
CONSORT	Consolidated Standards of Reporting Trials
CI	Chief Investigator
CM	Community Matron
CRF	Case Report Form
CTU	Clinical Trials Unit
eFI	Electronic Frailty Index
EQ-5D-5L	EuroQoL Descriptive System
fRCT	Feasibility randomised controlled trial
GP	General Practitioner
HRA	Health Research Authority
IRAS	Integrated Research Application System
LTC	Long term condition
LTC-6	Health Foundation Long Term Condition 6-item questionnaire
MCA	Mental capacity Act
MRC	Medical Research Council

NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NRES	National Research Ethics Scheme
PIS	Participant Information Sheet
PPI	Patient and public involvement
PRISMA7	Program of Research to Integrate Services for the Maintenance of Autonomy – 7 item tool
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SF-36	Medical Outcomes Study 36-Item Short Form Survey Instrument
SWCRN	South West Clinical Research Network
TMG	Trial Management Group
TSC	Trial Steering Committee
UCLA-3	UCLA 3-Item Loneliness Scale
VAS	Visual Analogue Scale

Chapter 1: Introduction

1.1 Thesis Aim

Frailty is a clinical syndrome associated with older age, which features deterioration across multiple body systems and is accompanied by increased vulnerability to adverse health outcomes (Clegg *et al.*, 2013). Frailty can be a devastating consequence of ageing, with older people who live with frailty experiencing higher death rates, hospitalisations, falls, and care home admissions than the non-frail, with poorer quality of life and more loneliness (Kojima *et al.*, 2016). This thesis reports the development of a nurse-led assessment and care planning intervention for community-dwelling frail older people and evaluates the feasibility of conducting a randomised controlled trial (RCT) of the implementation of this intervention in primary care.

To meet the challenges of a growing older population with a high prevalence of frailty, proactive, holistic, person-centred primary and community-based care is needed, and yet there is no accepted model or ideal intervention in these settings (Gardner *et al.*, 2017). Community-based frailty interventions should be clinically rigorous and time-effective and include appropriate screening methods, which enable resources to be targeted at patients who will benefit most (Fougere *et al.*, 2017). The content of this thesis adds to the existing evidence and addresses the methodological limitations of current research into complex interventions for older people who live with frailty.

1.2 Structure of the Thesis

This thesis presents the research journey from the initial co-production of the study and design of the intervention, the conduct of the mixed-methods feasibility study, through to conclusions and implications of this work. Chapter one sets the context for

the research with the background, literature review and significance of this work. Chapter two describes the co-production of the Holistic Assessment and care Planning in Partnership Intervention study (HAPPI), including the patient and public involvement (PPI) consultation, which informed the study design. Chapter three outlines the study methodology and theoretical paradigm that underpinned the research. The development of the HAPPI intervention, by means of an e-Delphi survey and research stakeholder consultation, is reported in chapter four. Chapter five details the methods of the feasibility randomised controlled trial (fRCT) with its embedded qualitative study. The results of the fRCT are reported in chapter six and the qualitative study findings in chapter seven; results are split into two chapters for ease of reading. Study results are discussed in chapter eight and chapter nine presents overall conclusions and recommendations for future practice and research.

In addition to illustrating the research process, the thesis captures the author's personal journey as an early career researcher and progression through a National Institute for Health Research (NIHR) career pathway. This began with a clinical academic internship, where the topic of frailty was extensively researched and the study objectives formulated. Broad patient and public involvement activity then led to the design of the study, and progressed to the Clinical Doctoral Research Fellowship, during which the study was conducted, leading to completion of the PhD. This is summarised in Figure 1.1.

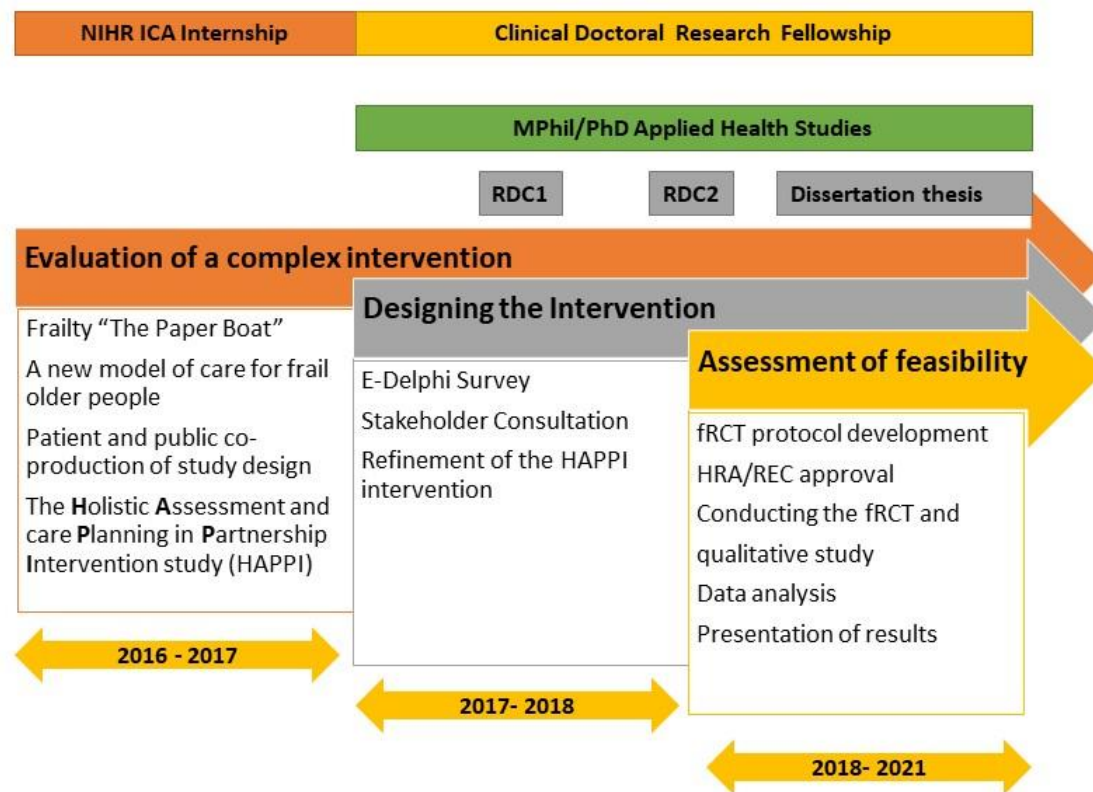


Figure 1.1: The research journey

1.3 Background: our ageing society and living with frailty

The UK population is ageing and, whilst this is undoubtedly a success for improved public health and welfare leading to longer life expectancy, it brings with it the challenge of meeting the health and social care needs of higher numbers of older people. Figures published by the Office for National Statistics in 2018 predict that, by 2066, there will be an additional 8.6 million UK residents aged sixty-five years and over, taking the total number in this group to 20.4 million or 26% of the population (Office for National Statistics, 2018a). Numbers of people aged eighty-five years and over are rising most rapidly. In mid-2016, there were 1.6 million people in this age group (2% of the total population) however, by mid-2041, this is expected to double to 3.2 million (4% of the population). Numbers are due to treble by 2066, to 5.1 million people, comprising 7% of the total UK population. In contrast, the population aged sixteen to sixty-four years is predicted to grow by just 2% over the next twenty-five years, leaving a significant gap between those contributing to pension and national insurance costs and the numbers of people who will require support from these funds.

Remaining life expectancy at aged sixty-five is currently eighteen years for men and twenty-one years for women. However, on average, we can expect to experience about ten years of diminished quality of life at the end of life, due predominantly to limiting disability and illness (Mortimer, 2015). Much of this disability and loss of function can be attributed to the development of frailty. In 2019, the UK Government launched its “Grand Challenge for Ageing” with a goal of enabling its population to experience at least five extra healthy, independent years of life by 2035 by helping people to remain independent and addressing risk factors for adverse events such as social isolation (UK Government, 2019). Funding has been allocated and projects commenced in some areas of the UK, but the impact is yet to be determined. If

initiatives such as these are not successful, it is possible that prolonged life expectancy of frail adults may result in expanded morbidity and disability and resultant decreases in *healthy* life expectancy (Kingston *et al.*, 2018). Therefore, frailty is an important public health issue for society, both now and in the future.

The term frailty has long been accepted in daily language, 2500 years ago, Buddha contemplated “How easily the wind overturns a frail tree” (Byrom, 2012, p.3). Recently, a UK geriatrician likened frailty to a paper boat; brightly painted and sailing happily on still waters, but one that will quickly sink without trace once the rain starts and the wind gets up (Cantley, 2018). Nonetheless, it is only in the last 40 years that frailty has become a recognised disorder in the field of research and more recently accepted as a treatable syndrome in clinical practice (Sieber, 2017). Frailty was first described in research literature in the 1970s as “failure to thrive” (Hodkinson, 1973, p.94) and throughout four decades of research, definitions have been evolving. Frailty does not yet have an internationally recognised standardised definition (Dent, Kowal & Hoogendijk, 2016), however, most definitions focus on frailty as an age-related clinical syndrome associated with loss of resilience:

“A multidimensional syndrome of loss of reserves (energy, physical ability, cognition, health) that gives rise to vulnerability.” (Rockwood *et al.*, 2005, p.489)

Frailty is associated with a multitude of adverse outcomes such as debility, falls, fractures, loneliness, poor quality of life, depression, cognitive decline, hospitalisation, loss of independence and care home admission (Hoogendijk *et al.*, 2019). These poor outcomes are costly to older individuals and to the health and social care system. In order to minimise cost and meet the needs and preferences of older people, there has been a policy move towards “ageing in place” (World Health Organization, 2015, p.36). This concept proposes that older people, irrespective of age, income and level of

disability should be supported to live safely, independently and comfortably at home if this is their preference. Not only is this viewed as the preferred option for individuals, it is thought to reduce health care expenditure (Beard *et al.*, 2016). This ethos has been adopted by the UK and other countries with policies and clinical practice aimed at providing frailty care away from hospitals and closer to people's homes (Imison *et al.*, 2017). However, it is not yet clear how this move from hospital-based, specialist care to generalist services delivered in low-intensity settings can be achieved, what the care models should encompass and which clinicians are skilled to lead and provide care (Hoogendijk *et al.*, 2019).

1.4 Current evidence

The following sections set the context for the remainder of this thesis, and highlight the current lack of evidence for nurse-led management of frailty in older people within primary care in the UK. Firstly, the impact of frailty is presented and secondly, its pathophysiology is explored. Thirdly, the established and emerging models of frailty are introduced and fourthly, the management of frailty is discussed. Finally, frailty management in primary care is presented with a focus on the role of nurses working in partnership with frail older people.

1.4.1 The Impact of Frailty.

As individuals age, their mortality risk escalates, according to Gompertz's law (Gompertz, 1825). However, people do not die of old age, rather they amass a variety of age-related conditions and so become increasingly susceptible to dying from various internal and external stressors. Ageing is normal in all species and is characterised by catabolism, degeneration and functional loss in body organs leading to progressive reliance on reserves to maintain homeostasis (Sieber, 2017). Physiological changes of ageing are exacerbated by co-existing disease and deterioration is progressive but

heterogeneous with a variable rate of decline (Navaratnarajah & Jackson, 2017). This means that individuals age differently, but generally, in older age, impaired physical and mental function leads to limitations in activities of daily living and ultimately loss of independence.

Ageing, accompanied by a loss of physiological resilience, manifests as the clinical syndrome of frailty (Clegg *et al.*, 2013). Accurate estimates of global frailty prevalence are not available. The majority of frailty research has been conducted in higher-income countries, with a paucity of research in poorer countries and a variety of definitions of frailty used (Hoogendijk *et al.*, 2019). This means there are no globally accurate prevalence figures. However, one systematic review combined findings from 61,500 older participants (minimum age sixty-five and no maximum age) and found a weighted average estimate of 11% for frailty, but noted a variation of between 4% and 59% across studies (Collard *et al.*, 2012). In England, overall prevalence of frailty is 14%, 6.5% in those aged 60-69 years and rising to 65% in those aged 90 years and above (Gale, Cooper & Aihie Sayer, 2015).

Over decades, ill health has been reducing in older age, mainly because of healthcare quality improvement and health behaviour change (Cutler, 2001), however, this trend is changing (Martin *et al.*, 2010). Higher-income countries are now experiencing an increase in early disability among mid-adulthood (ages fifty to sixty-four) due to lifestyle factors and the earlier development of long-term conditions such as ischaemic heart disease and diabetes. This situation raises an important economic challenge. This cohort of new older people with moderate to severe functional limitation is expected to live for a longer period of time and consume proportionally larger amounts of healthcare resource. Consequently, there is a policy drive to develop new models of care, usually in non-acute settings, aimed at meeting the needs of this population at

lower cost to ensure that sufficient funds are available to provide services for the larger numbers of people who will be living with frailty (Beard *et al.*, 2016).

In high-income populations, numbers of frail people are expected to rise as life expectancy continues to increase in these countries (Kingston *et al.*, 2018). Studies show increased healthcare expenditure for older people with higher levels of frailty due to greater in-patient use including admissions and bed days, post-acute care, and outpatient care (Ensrud *et al.*, 2018; García-Nogueras *et al.*, 2017; Sirven & Rapp, 2017). A recent UK study calculated the extra annual cost to the healthcare system associated with frailty (Han *et al.*, 2019) as £561.05 per person for mild frailty, £1,208.60 for moderate frailty and £2,108.20 for severe frailty. This equates to a total additional cost of £5.8 billion per year across the UK. Thus, despite frailty having a negative impact on longevity and quality of life for individuals and its cost to society as a whole, it remains a poorly managed clinical syndrome (Harrison *et al.*, 2015).

Harrison *et al.* (2015) called for frailty to be conceptualised as a long-term condition to promote earlier identification, prevention and effective management, however, robust clinical knowledge of the pathophysiology of the syndrome is lacking, leading to ongoing debate about its management in different healthcare sectors.

1.4.2 The Pathophysiology of Frailty

Frailty is thought to result from cumulative cellular damage over the life course (Cesari, Vellas & Gambassi, 2013; Rockwood & Mitnitski, 2007). Although its specific pathophysiology is not fully understood, it is known to follow similar mechanisms to sarcopenia (muscle weakness) (Jeejeebhoy, 2012) and malnutrition (Cesari *et al.*, 2014b) accompanied by de-regulation of inflammatory processes (Li, Manwani & Leng, 2011). Frailty is not natural ageing; rather it develops when multiple body systems fail. As individuals age, the more systems that fail, the more likely it is that the person will

become frail (Clegg *et al.*, 2013; Morley *et al.*, 2013). Recent literature has focussed on a continuum of change, from healthy ageing to the development of long-term conditions, then to multimorbidity (defined as the presence of two or more long-term conditions) and lastly to frailty, predominantly towards the end of life (Franceschi *et al.*, 2018). In this model, frailty is a “multisystem ageing syndrome” (Thillainadesan, Scott & Le Couteur, 2020, p.758) that represents the later stages of ageing that occur in people who have not died of other causes earlier in life.

As people move along this continuum, there is a loss of physiological reserve in all body systems. Normally, there is an intrinsic reserve buffer, thought to be about 30%, which enables homeostasis to be maintained and good function preserved. Once this threshold is breached, then frailty will result as repair mechanisms can no longer maintain homeostasis (Lang, Michel & Zekry, 2009). This leads to loss of resilience, or loss of ability to “return to basal state” (Woo, 2019, p.68) when faced with a stressor. Clinically, this means that a frail person will not recover in a timely manner compared to a non-frail person from a stressor such as minor illness or change to social circumstances. Over time, this leads to functional deterioration and loss of independence. In addition, pre-frailty can be described as the “silent precursor” (Dent, Kowal & Hoogendijk, 2016, p.4), which converts to frailty in seemingly robust individuals when certain external factors are present, such as acute illness, injury or stress (Clegg *et al.*, 2013). Other independent risk factors for frailty development have been identified including loneliness (Gale, Westbury & Cooper, 2018), deprivation (Hoogendijk *et al.*, 2014), depression (Vaughan, Corbin & Goveas, 2015), low physical activity and polypharmacy (Heuberger, 2011). With its plethora of risk factors affecting all body systems, frailty is clearly a multifactorial syndrome that can be challenging to address. This has led to the development of several models describing causation and

proposing clinical management strategies which will be discussed in the next section of this thesis.

1.4.3 Models of Frailty

Given its pathophysiology, contributory risk factors for frailty can be clinical, functional, behavioural, biological, psychological, emotional and social, consequently, a broad range of expertise is needed to identify relevant risks and support the older person to manage them (Dent, Kowal & Hoogendijk, 2016). Risk factors are not always obvious and older persons, who do not tend to perceive themselves as frail, may not recognise or acknowledge the risks (Nicholson, Gordon & Tinker, 2017). Frailty is unpredictable, it can fluctuate and there can be sudden deterioration and so the potential to be proactive can be lost (Stolz, Mayerl & Freidl, 2019). In order to better comprehend, research and clinically manage frailty, several biomedical models have been proposed including those that are rules-based using the presence of defined symptoms (Fried *et al.*, 2004) or those that total numbers of impairments (Rockwood *et al.*, 2005). These biomedical models have dominated the literature of the past forty years, however, newer models acknowledge a more holistic approach integrating a broad range of risk factors and their management. In recent years, clinical and nonprofessional definitions of frailty have diverged, the former focusing on biomedical risks and the latter on the social consequences (Morden, Jinks & Ong, 2012; Nicholson, Gordon & Tinker, 2017). Both the established and the emerging models will be discussed in sections 1.4.3.1 and 1.4.3.2.

1.4.3.1 Established Models

Two models of frailty have dominated research and clinical (predominantly medical) practice; Fried's phenotype model (Fried *et al.*, 2004) and Rockwood's cumulative deficit model (Rockwood *et al.*, 2005). Both models have been extensively utilised in

research studies but were originally developed for different purposes. The phenotype model claimed to diagnose frailty whilst the cumulative deficit model calculates frailty risk (Cesari *et al.*, 2014a).

Fried's phenotype model offers five descriptors: self-reported exhaustion; reduced muscle strength; low physical activity; slow walking speed; and unintentional weight loss. If a person displays three or more of these symptoms they are considered to be frail (Fried *et al.*, 2004). This model can be used in clinical practice during a consultation with a patient and is useful for prognostication as it strongly predicts adverse outcomes of falls, hospitalisation, disability and death. Rockwood's model takes a quantitative approach to describing frailty as the accumulated sum of a number of problems or deficits; the greater the number of deficits, the higher the probability that adverse outcomes are likely (Rockwood *et al.*, 2005). Both models have been criticised in that they do not take into account psychological or cognitive domains of frailty (Berrut *et al.*, 2013) and consequently do not provide a holistic framework for its management.

1.4.3.2 Emerging Models

In acknowledgement of the need for a more holistic approach to frailty management, there has been a move towards life-course and assets-based conceptualisations of frailty. This change has grown out of evolving research in which older people have rejected the term "frailty" as irrelevant or stigmatising based on its focus on the negative aspects of ageing (Britain Thinks, 2015). It would appear that people resent the term frailty and perceive that it signals a self-perpetuating cycle into decline (Warmoth *et al.*, 2016). Participants in Warmouth's study, who objectively met frailty criteria, willingly portrayed their health conditions and physical limitations but did not self-identify as frail. Other researchers have found that reasons given for limitations and loss of independence were often perceived as relating to psychological and social factors

rather than physical conditions (Grenier, 2006). Understanding older peoples' perspectives on frailty is important when delivering an appropriate person-centred approach to frailty assessment and management, as using inappropriate terminology can provoke an emotional reaction and may lead to older people rejecting services (Puts *et al.*, 2017).

Taking into account older people's views on using frailty as a diagnostic label, it could be argued that taking a wholly biomedical approach has caused clinicians to neglect personhood and disregard existing strengths and assets. In this context, assets can include the person's own resources, abilities and capabilities (National Institute for Health and Care Excellence, 2019a). Ignoring these assets can miss opportunities for health improvement and lead to tension in the person-clinician relationship (Rahman, 2018). Identifying assets means there is a recognition and inclusion of the full range of available resources that can be used to protect individuals against negative health outcomes and it takes a more holistic, multidimensional approach to managing these outcomes. This concept has been adopted by the World Health Organisation who have promoted intrinsic capacity as a quantifiable measure of healthy ageing (World Health Organization, 2015) and a composite measure of all physical and mental capabilities of an older person (Woo, 2019). The construct of intrinsic capacity moves away from the biomedical approach of diagnosing and treating diseases, and towards assessment of body functions as a "holistic entity" (Cesari *et al.*, 2018, p.3), supporting prevention or managing deterioration, aiming always to preserve function and independence. This is more in tune with older people's perceptions of becoming frail in terms of everyday tasks and how it feels if these tasks start to become difficult to complete, thus eroding independence and wellbeing (Britain Thinks, 2015).

Another conceptualisation of frailty promotes a life course approach (Gill *et al.*, 2006). Frailty is viewed as a dynamic trajectory, which progresses and recedes over the life-course (Trevisan *et al.*, 2017). Progress along this trajectory is influenced by individualised factors from earlier life that can predict age-related health and morbidity. These include wider determinants of health such as education, ethnicity, gender, geography, financial hardship, occupation, physical activity, smoking and body mass index (Hale, Shah & Clegg, 2019). This means that there are opportunities for prevention and prognostication at all stages of the life-course and that mid-life social, behavioural and biomedical risk factors can be modified altering the frailty trajectory thus avoiding adverse outcomes.

In 2015, the National Institute for Health and Care Excellence (NICE) published a guideline entitled “Dementia, disability and frailty in later life – mid-life approaches to delay or prevent onset” (National Institute for Health and Care Excellence, 2015). This encouraged health and local government organisations to develop population-level initiatives to address lifestyle issues, with the aim of preventing frailty and promoting healthy ageing. However, as previously discussed, the majority of older people are not frail and so a systematic method of identifying the frail cohort is required to target prevention and management strategies effectively. Multiple studies have attempted to address this deficit by developing frailty screening instruments. The next section of this review examines the evidence for their use.

1.4.4 Screening for frailty

The combination of increasing prevalence of frailty and its association with adverse health outcomes would seem to make screening for frailty appropriate, particularly in primary care, where the majority of older people access health services. In addition, early identification of frailty enables the design of population-based preventative

interventions to target known risk factors (Santos-Eggimann & Sirven, 2016).

However, population screening for frailty poses significant challenges. There is low awareness of frailty among older people who may view it as natural ageing and among some clinicians who may not have access to specialist treatment options (Ambagtsheer *et al.*, 2019). Although early frailty has the potential for treatment and reversibility (Travers *et al.*, 2019), response to treatment is variable and there is less evidence of response as frailty becomes more severe. Furthermore, primary care is already overburdened with screening activity, so a simple, validated tool or method to identify and stratify frailty is needed.

Multiple studies have proposed instruments to screen for and measure frailty (Pialoux, Goyard & Lesourd, 2012), some are simple and some more complex. Two common approaches are questionnaires that assess frailty characteristics or the use of physical markers for frailty, such as gait speed and hand grip strength. A systematic review by Clegg *et al.* (2015) evaluated screening tools that had been validated in clinical trials for their application in primary care. These included four metre gait speed measurement (Castell *et al.*, 2013), timed-up-and-go-test (TUGT) (Savva *et al.*, 2013), the use of questionnaires such as the Groningen Frailty Indicator (Hoogendijk *et al.*, 2013) and the PRISMA-7 tool (Raiche, Hebert & Dubois, 2008). This review found that four metre gait speed, PRISMA-7 and the TUGT had the highest sensitivity for frailty identification, but all tests displayed limited specificity resulting in high numbers of false positives. They concluded that no one test is accurate enough to diagnose frailty in primary care. A later study by Lee *et al.* (2017a), found that a combination of measurement of gait speed and grip strength was sensitive and specific as a proxy for the Fried frailty phenotype (Fried *et al.*, 2004) with a higher positive predictive value than either gait speed or grip strength alone. Ideally, a simple investigation such as a

blood test could be a viable solution, however, a review of biological markers for frailty did not find one single marker that would be diagnostic (Lee *et al.*, 2017b).

Given concerns about primary care capacity and workload (Shaw *et al.*, 2018), there has been a move in recent years to provide easy and rapid approaches to frailty identification (Ruiz *et al.*, 2020). This has led to the development of automated tools that can be populated by information from the clinical record and provide lists of frail people within a general practice population. The most developed tool is the electronic frailty index (eFI) (Clegg *et al.*, 2016). The eFI is a computerised algorithm developed using data from 900,000 older people's UK primary care records. It is based on the principles of the cumulative deficit model of frailty (Rockwood *et al.*, 2005) and calculates a frailty score based on the occurrence of up to 36 deficits, taking information from the primary care clinical record (Alharbi *et al.*, 2020). Frailty scores are then categorised into four levels of frailty severity; fit, mildly frail, moderately frail and severely frail (Table 1.1). The eFI has an advantage over other tools in that it is fully automated and, therefore, is time-efficient and does not require any clinical knowledge to produce a full list of frail patients within a general practice population.

Table 1.1: eFI scores to categorise severity of frailty

Severity of frailty	Score range
Fit	0.00 - 0.12
Mild	0.13 – 0.24
Moderate	0.25 – 0.36
Severe	> 0.36

The eFI has been shown to have robust predictive validity for mortality, hospitalisation and care home admission (Clegg *et al.*, 2016) and convergent validity (Brundle *et al.*, 2019) with a strong correlation with other frailty screening tools including the Clinical Frailty Scale (Rockwood *et al.*, 2005) and the Edmonton Frail Scale (Rolfson *et al.*, 2006). Nonetheless, the eFI is a risk stratification tool that is known to result in false positives, therefore, it is recommended that frailty diagnosis is confirmed either by using another screening tool or clinical judgement (NHS England, 2017). The eFI has been embedded into clinical records systems in the majority of general practices in England. The general practice contract mandates the requirement to identify moderately and severely frail patients and employ limited clinical interventions. These interventions include yearly medication reviews (severely frail only), annual falls risk identification and to promote the use of the additional information in Summary Care Record.

Whatever tool is used, once frail people have been screened for and identified, frailty requires management and treatment as with any other long-term condition (Harrison *et al.*, 2015). The following section of this review examines the current approaches to the management of frailty and their evidence base.

1.4.5 Managing Frailty

As evidenced in section 1.4.3, frailty can be managed by interventions addressing individualised, relevant risk factors (Clegg *et al.*, 2013). Many of the symptoms of frailty, which lead to loss of independence, can be improved and even reversed with relatively simple measures. For example, exercise and addressing visual impairments can prevent falls (Chan *et al.*, 2017; Morley, 2017). Weight loss and malnutrition that accompany frailty can be managed using nutritional supplementation (Landi *et al.*, 2016). Polypharmacy and adverse effects of medication are common causes of

cognitive decline, which can be addressed by an effective medication review (Morley *et al.*, 2015).

This holistic, individualised approach is the founding principle of a comprehensive geriatric assessment (CGA), which is described as the gold standard intervention for the management and prevention of deterioration in frailty (Gladman, 2016). The most widely accepted definition of CGA is:

“a multidimensional, multidisciplinary process which identifies medical, social and functional needs, and the development of an integrated/co-ordinated care plan to meet those needs.” (Parker *et al.*, 2018).

CGA is part of routine care and is well evidenced in the acute hospital setting within the speciality of geriatric medicine. A systematic review by Ellis *et al* (2011) found that patients who experienced CGA in hospital were more likely to be alive and in their own homes at up to six months following discharge, were less likely to be institutionalised or suffer deterioration and death. However, the efficacy of CGA is not well established in other healthcare settings, such as primary care, despite the shift of international policy direction towards ageing in place with care and support close to home (World Health Organization, 2015).

It has been proposed that the provision of coordinated, person-centred care is preferable to support the older person in managing complex health needs at home (Goodwin, 2013). The National Coalition on Care Coordination (2018) developed a blueprint for care coordination that includes: being patient centred; taking a multi-professional approach connecting health and social services; using a comprehensive assessment; and executing and monitoring a flexible care plan in partnership with the patient. Thus, there is a largely consensual understanding of what successful approaches to person-centred care outside of hospital for frail older people should look like (Goodwin, 2013). However, lack of research in this area means there is insufficient

evidence to support a positive association between this care model and improved patient experiences, clinical outcomes and financial savings (Imison *et al.*, 2017). The following section will explore the evidence to date and identify the research deficiencies.

1.4.6 Frailty Management in Primary Care

In the UK, risk management of frailty to prevent future deterioration leading to secondary care usage has been encouraged (La Grouw, Bannink & van Hout, 2020). With its ease of accessibility, established relationships between general practitioners and their patients and access to a multidisciplinary team, primary care has been seen as a suitable setting for the management of frailty (Drubbel *et al.*, 2013). The British Geriatrics Society (BGS) in 2014 suggested that a primary care led 'holistic review' by a GP or specialist nurse may enable more frail older people to access services out of hospital (British Geriatrics Society, 2014). Despite this guidance, implementation of primary care frailty management remains problematic with reports that general practitioners view frailty screening as a burden within an already challenging workload (Reeves *et al.*, 2018). Concerns have been raised across Europe about the time taken for identification of the frail population, conducting a CGA and the additional cost in time and resources to primary care (Shaw *et al.*, 2018).

Notwithstanding these concerns, there is no evidence to indicate that the acute hospital CGA framework is immediately transferable or that primary care clinicians possess the specialist skills and knowledge to deliver this care. Furthermore, there is no one specific, validated CGA model for use in primary care. The delivery of complex interventions for older people at home can reduce care home and hospital admissions and falls, however, there is less certainty around the benefit of any specific type or intensity of intervention (Beswick *et al.*, 2008). In addition, Beswick *et al.*'s systematic

review revealed that there was a lack of identification and recruitment of frail older people to studies and, therefore, the additional benefits of targeting the frail population, as opposed to all older people, are not known.

A systematic review of one primary care CGA tool noted a lack of an agreed implementation model and concerns of workforce capacity in UK primary care (Craig *et al.*, 2015). A review that attempted to identify short, validated approaches to CGA in primary care found several tools but identified the need for more research into approaches addressing the implementation of an integrated, holistic CGA in a primary care setting, including what is feasible for large numbers of the population (Morley *et al.*, 2017). It seems possible that whilst the principles of CGA are appropriate for primary care delivery, the practicalities of its implementation, including which clinicians should lead the process, require further exploration. Interest in this topic has gained traction with the James Lind Alliance naming optimal delivery of CGA in different healthcare settings as one of the top ten research priorities for older people (James Lind Alliance, 2018).

1.4.7 Nurse-led Frailty Interventions in Primary Care.

Some authors have evaluated health care clinicians' attitudes to frailty assessment and management and found more positive engagement among nurses than other clinicians (Moffatt *et al.*, 2018). In the UK, The Royal College of General Practitioners have advocated the use of a broader skill mix in primary care where nurses and other clinicians deliver care coordination (NHS England, Royal College of General Practitioners & Health Education England, 2016). It would appear that the BGS recommendation that holistic assessment of frail older people in primary care should be led by nurses would seem appropriate. However, the nursing contribution to the management of frailty is poorly developed. A literature search conducted to inform this

review (Appendix 1) revealed that studies assessing nurse-led interventions have shown mixed results. Five studies reported positive effects of nurse-led interventions (Berglund *et al.*, 2015; Bleijenberg *et al.*, 2017b; Kono *et al.*, 2016; Melis *et al.*, 2008; Rockwood *et al.*, 2000), four reported both positive and negative effects (Bleijenberg *et al.*, 2017a; Schein *et al.*, 2005; Stijnen *et al.*, 2014a; Taube *et al.*, 2018) and seven reported no effect on outcomes (Bouman *et al.*, 2008; Godwin *et al.*, 2016; Hoogendijk *et al.*, 2016b; Metzelthin *et al.*, 2010; Suijker *et al.*, 2016b; Van Hout *et al.*, 2010; van Lieshout *et al.*, 2018). It is clear that there are some methodological challenges that may have affected results, including heterogeneity of participants, which the authors acknowledge and recommend are addressed in future research.

As discussed in section 1.4.4, identifying and targeting the frail population is problematic as there is no definitive definition of frailty and a variety of screening tools and other methods of case finding have been used. Furthermore, there is no consistency of screening methods across the studies and, indeed, some made no attempt to target frail people within the older population (Godwin *et al.*, 2016; van Lieshout *et al.*, 2018). Authors acknowledge that including the non-frail population may leave little room for improvement in some outcomes (Bleijenberg *et al.*, 2017a). In addition, there may be benefit in selecting groups of the frail population including the oldest-old i.e. those aged eighty years and over (Bleijenberg *et al.*, 2017b).

Other authors, in critiquing the studies above, reported that there was a lack of specialist older persons' knowledge and skills amongst the nurses, as well as a need for possession of more advanced assessment skills to ensure effective delivery and fidelity to the intervention (Hertogh & Bastiaans, 2016; Hoogendijk, 2016b). Some authors have suggested that primary care teams require the support of specialist services, such as geriatricians (Hertogh & Bastiaans, 2016), whilst others have

employed nurses with advanced assessment and case management skills and reported more positive effects on outcomes (Kono *et al.*, 2016; Rockwood *et al.*, 2000). In addition to advanced clinical skills, several studies have highlighted the importance of a goal-orientated intervention focussing on person-centeredness and self-management. This approach should be built on a caring, supportive relationship between nurse and patient (Imhof *et al.*, 2012).

Studies focussed on a variety of outcome measures, including function and independence, quality of life, care needs and mortality (Berglund *et al.*, 2015; Kono *et al.*, 2016; Melis *et al.*, 2005; Rockwood *et al.*, 2000). Despite this multiplicity of outcome measures, evidence is lacking in relation to which outcomes are important to frail older people themselves or which might be amenable to a person-centred intervention. This makes comparison across studies problematic. Health-related quality of life is an important outcome measure for this population group, however, study methods need to address the issue of demonstrating quality of life improvement when frailty is a declining trajectory. Imhof *et al.* (2012) suggest the need to combine quality of life outcome measures with assessment of function to provide a more holistic picture of independence.

Highlighting the need for holistic, person-centred outcome measures, some studies have suggested that care is needed in the choice of intervention components in order for them to have maximum effect. These include assessment of falls, medications, pain and long-term conditions management (Stijnen *et al.*, 2014a). However, other studies emphasise the importance of non-medical solutions including environmental, social support and housing to ensure a holistic, multidimensional assessment process (Hoogendijk *et al.*, 2016b; Schein *et al.*, 2005). This provides an additional challenge

to ensure primary care nurses are able to access wider social and environmental support as part of the assessment process.

Finally, the majority of the research carried out into the efficacy of nurse-led and coordinated care for frail older people has been conducted in The Netherlands; in this case eleven out of the seventeen studies reviewed. Nine of the Dutch studies demonstrated no effect, or mixed effects of the intervention (Bleijenberg *et al.*, 2017a; Bouman *et al.*, 2008; Hoogendijk *et al.*, 2016b; Metzelthin *et al.*, 2010a; Stijnen *et al.*, 2014a; Stijnen *et al.*, 2014b; Suijker *et al.*, 2016; van Hout *et al.*, 2010; van Lieshout *et al.*, 2018). Emiel Hoogendijk provided critique of some of these studies which formed part of the Dutch National Care for the Elderly Programme and considered the difficulty of demonstrating the effect of these interventions (Hoogendijk, 2016). He concluded that the Netherlands already had a strong primary care approach to supporting older people and, therefore, these new care models offered little advantage over the existing care and support. He advocated that more research was needed to determine whether these findings from the Netherlands differ from other countries whose primary care systems, while strong, are not necessarily focussed on older people, such as the UK and Finland.

In 2019, NHS England published “The NHS Long Term Plan”, which set out plans to ensure appropriate funding for services, including those in primary care (NHS England, 2019). It specifically highlighted the needs of frail older people suggesting there should be a systematic method to allow early detection of frailty and the development of integrated services to work with older people to maintain their independence. Under the terms of the NHS England General Practice Contract 2017/18, to facilitate the identification of frail older people, general practices were required to identify patients aged 65 years and over, who are living with moderate or severe frailty using an

appropriate, evidenced based tool such as the electronic frailty index (eFI). Building on the UK policy direction, the BGS issued a Position Statement on Primary Care for Older People (British Geriatrics Society, 2018), proposing a multi-professional approach to supporting frail patients once they are identified, and highlighted evidence that nurses and allied health professionals can successfully lead and input into the assessment and care planning process (Schadewaldt *et al.*, 2013).

1.5 Significance of this research

This review of the literature has demonstrated the challenges of evaluating primary care interventions for frail older people. Evidence to date concludes that mechanisms of effect are unclear, outcome measures are multiple and confused and interventions often poorly reported and, therefore, not replicable (Gardner *et al.*, 2017). In examining the evaluation of complex healthcare interventions, Greenhalgh and Papoutsi note that much of what is named as complexity research does not in fact engage with complexity and that there is a need for “in-depth, mixed-methods studies” (Greenhalgh & Papoutsi, 2018, p.1092) and process-based approaches to understand dynamic, real-life healthcare. This study aims to address this deficiency through the use of mixed-methods to gain a deeper and richer understanding of the potential barriers and enablers to nurse-led primary care for frail older people.

Other gaps in the evidence base have been revealed. Studies have concluded that some frailty interventions are ineffective, when in reality, flaws in study design may have impacted on their ability to show an effect. Such issues include a lack of identifying and targeting the frail population (Christensen *et al.*, 2017; Fougère *et al.*, 2017); ineffective components of the intervention (Li *et al.*, 2017); lack of clinician skills and knowledge in delivery of the intervention (Hertogh & Bastiaans, 2016); poor fidelity

to the intervention (Bleijenberg *et al.*, 2016b; Suijker *et al.*, 2016b) and use of inappropriate outcome measures (Bleijenberg *et al.*, 2016a; Gardner *et al.*, 2017).

Utilising a mixed-methods approach, the research presented in this thesis addresses these limitations in a number of ways. Through the HAPPI feasibility study, the use of an automated, systematic method of frailty diagnosis and participant identification using the electronic frailty index (eFI) has been evaluated. Furthermore, it has been possible to implement and test, for the first time, the acceptability of a unique person-centred intervention, which has not been prescribed or regimented but instead, developed iteratively based on the needs and aspirations of frail older persons. Finally, extensive testing of feasibility parameters to maximise recruitment and retention and to determine the acceptability of the intervention allowed further exploration of the views of participants, carers and clinicians. The phases of this study and methods used to address the research aims are summarised in Figure 1.2.

Research Aim: To develop, implement and test a nurse-led **H**olistic **A**ssessment and care **P**lanning in **P**artnership **I**ntervention (**HAPPI**) and to determine important parameters for the design of a definitive RCT

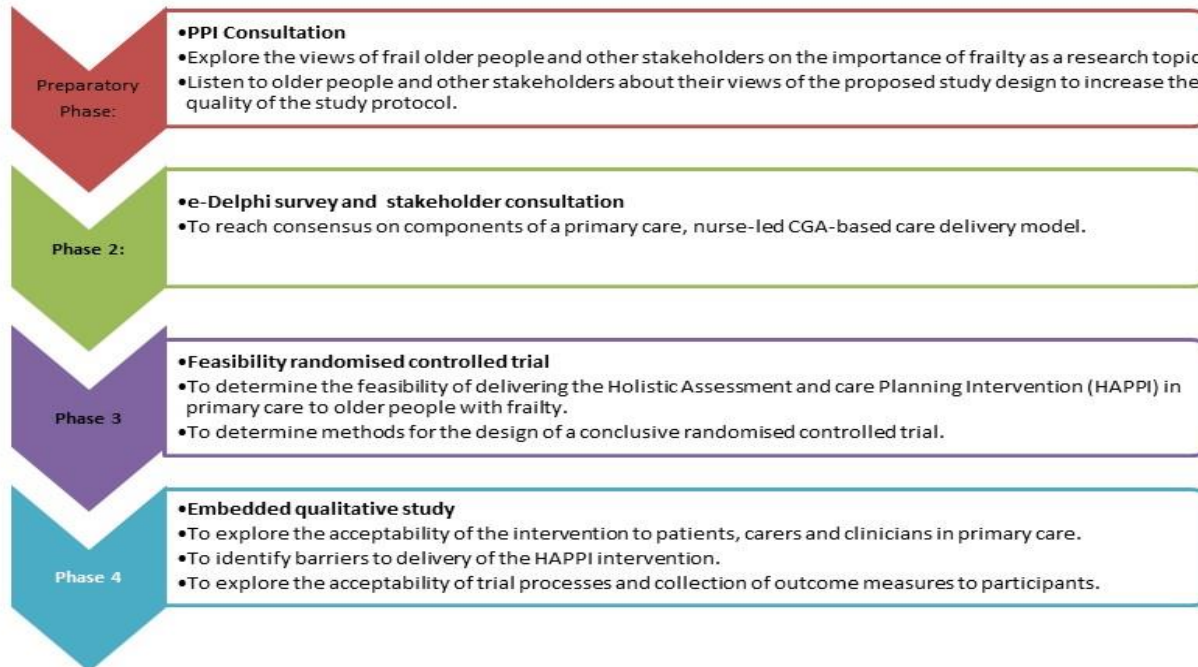


Figure 1.2: Study phases and research aims

1.6 Chapter Summary

Whilst conceptualisation and definition of frailty continues to evolve, it is clear that it is a complex syndrome, existing not only as a clinical state but also as a lived experience. It requires researchers and clinicians to understand that the health and psychosocial problems that accompany it are inseparable. Therefore, any intervention introduced to treat and manage frailty should, ideally, be holistic and wholly person-centred. There is currently no standardised treatment protocol and any future approach should ensure that all interventions are developed in partnership with the frail person. Clinicians too must take a multi-dimensional approach to assessment and planning care.

The evidence has indicated that, to meet the challenges of frail older people and to provide proactive, holistic care close to home, there is a need for a person-centred intervention to be developed, which could be implemented in primary care. It must be feasible to be delivered in this setting and have a high level of specificity to enable primary care resources to be targeted at patients who will most benefit from the intervention. It is not yet clear if this intervention can successfully be delivered by nurses.

The HAPPI study has been designed to address the identified research gaps and to fully explore the issues of feasibility and acceptability. The next step involved frail older people and their carers working with the researcher to co-design the feasibility study. This consultation and involvement is reported next in Chapter two.

Chapter 2: Co-production of the research study

The HAPPI study was co-produced in partnership with older people, carers and clinicians. The National Institute for Health Research (NIHR) guidance defines patient and public involvement (PPI) in research as:

“... an approach in which researchers, practitioners and the public work together, sharing power and responsibility...”

(National Institute for Health Research, 2018, p.4).

One of the key principles, of effective PPI as defined by the NIHR, is to include the perspectives and skills of all those who can make a contribution, and so authentic consultation with stakeholders was seen to be a vital step in the design of this study. The concept of frailty may have emotive and negative connotations for older people and carers, with research noting that older people did not always relate to the term ‘frailty’ but do articulate clinical features relating to loss of independence and ability to cope at home (Britain Thinks, 2015).

In order to increase the likelihood of a successful study, it was important to involve older people and their carers from the outset. This included understanding their perspectives of living with frailty to ensure sensitive methods of recruitment and retention designed to maximise participation in the study. Similarly, as a feasibility study, involving clinicians who would be delivering the intervention was essential in ensuring the design was rigorous and fit for purpose. The content below has been submitted as a manuscript for publication to BMC Family Practice and the format of this chapter reflects the submitted manuscript. The manuscript is currently under review. An estimated percentage of contribution (%) of each author is as follows: Lyndon, H. (85%), Latour, J.M. (5%), Marsden, J. (5%), Kent, B. (5%). The percentages of contributions have been agreed among all authors.

Involving older people who live with frailty and health care professionals in designing a study to investigate effective clinical interventions in primary care.

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2.1 Abstract

Background: Frailty is a clinical syndrome associated with older age and characterised by loss of reserves and functional capability. This patient and public involvement (PPI) consultation aimed to explore views of older people with frailty, their carers and health care professionals on the importance of developing and implementing a nurse-led holistic assessment and care planning intervention and a proposed study design to test the intervention and its delivery including, outcome measures, recruitment and retention methods.

Methods: A consultation with frail older people, their carers and health care professionals using involvement frameworks as advocated for patient and public involvement by the National Institute for Health Research (NIHR). Data was collected through six individual face-to-face interviews with moderately and severely frail older people and, where possible, their carers. A semi-structured interview guide was developed and used to facilitate a conversation around the main topics of the proposed study design. Data was collected from health care professionals using a focus group and questionnaire.

Results: Older people and carers communicated their experiences of living with frailty and the difficulties presented. These challenges were categorised into four main themes; (1) the characteristics of frailty (2) the challenge of managing multiple long-term conditions, (3) organising care and support and (4) concerns about losing independence and the links to social isolation and loneliness. Health care professionals identified current barriers to effective frailty management in community care including an increased focus on acute care in the community with less time to complete thorough assessments and plan care. They highlighted having less time to be proactive and preventative.

Conclusions: This consultation reinforces the importance of early involvement of older people, their carers and other stakeholders in designing and planning research studies.

2.2 Plain English summary

Frailty can be a distressing but not inevitable part of getting older. People who are frail may feel more tired and weak than normal, have trouble getting around, lose weight and feel that they are slowing down. Frailty may lead to losing independence, hospital admissions and moving to a care home. Previous research has suggested that it may be possible to support older people to manage frailty like any other long term condition. If recognised early, we can provide care and support that may delay or prevent negative effects of frailty so that older people can retain their independence and quality of life. To do this, people need effective support at home from health services such as doctors and community nurses.

Our research aims to explore how community nurses can provide individualised support to older people who live with frailty. In order to ensure the study meets the needs of older people we have involved them in developing this research. We have consulted via interviews with older people who live with frailty and their carers. They felt that our proposed research was an important priority for them and suggested outcomes that were significant to them. They told us that they would want co-ordinated care led by a doctor or a nurse delivered close to home. We also spoke to general practitioners and community nurses who agreed with the suggestions of the older people and suggested we explore any barriers to providing care for frail older people in primary care.

2.3 Introduction

Patient and Public Involvement (PPI) in Research is essential to inform all stages of the research process (National Institute for Health Research, 2012). The term 'public' includes patients, carers and people who use health services as well as other stakeholders. Involving patients and the public in the design of a research study is important to make studies more effective, credible and relevant to the population group (Iliffe, McGrath & Mitchell, 2013). It can be seen as a core democratic principle that people who are affected by research have a right to influence what and how publicly-funded research is undertaken (National Institute for Health Research, 2012). Public involvement in research can lead to empowering people who use health and social care services, providing a route to influence change and improvement in issues that concern people most.

Evidence suggests that older people are often under-recruited in clinical trials (McMurdo *et al.*, 2011). Therefore, effective PPI at the early stages of studies that explore frailty management might provide insight into their needs and improve recruitment. Increasing the participation of older people in research can improve the generalisability of research findings and inform best practice. This paper describes the process undertaken to involve older people and health care professionals in the development of a study investigating how community health services can best support older people living with frailty to improve their quality of life

The research team planned to carry out a mixed methods feasibility study with the aim of developing and testing a nurse-led holistic assessment and care planning intervention and to determine important parameters for the design of a definitive randomised controlled trial (RCT). Prior to initiating the study, the research team identified important stakeholders as frail older people themselves, their carers and the

health care professionals who support them in primary care. This highlighted the importance of undertaking a consultation with older people who live with frailty and other stakeholders to further comprehend the challenges experienced by them to provide information on whether frailty and support to manage it was a priority for research and if so, how best to engage participants in the study. Frail older people, carers and health care professionals in primary care were approached as Specialist Advisors and the PPI consultation undertaken with them is described in this paper.

2.4 Aim

The aim of this PPI consultation was to:

- a. Explore the views of frail older people and other stakeholders on the importance of frailty as a research topic.
- b. Listen to older people and other stakeholders about their views of the proposed study design to increase the quality of the study protocol.

2.5 Methods

The NIHR INVOLVE Briefing Notes for Researchers: public involvement in NHS, public health and social care research (National Institute for Health Research, 2012) were used as a framework for the involvement process. The research team used qualitative methods, including interviews, a focus group and questionnaires, with subsequent data analysed using content analysis.

Eight moderately or severely frail older people, and forty-five health care professionals were approached to act as Specialist Advisors to be involved in the consultation round. One of the older people had a carer who also agreed to participate. Six older people agreed to be interviewed. The approach was made via their primary health care professional in this case the Community Matron (CM) who identified moderately and

severely frail older people from their existing caseloads who were interested in fulfilling the Specialist Advisor role and put them in touch with the research team. CMs were issued with an information leaflet to share with patients and carers (Figure 2.1) and were briefed on how to make the initial approach. Once initial agreement to participate was given, the investigator contacted the older person and/or their carer to give more information, answer any questions and offer a face-to face interview in their home. This method of original approach via the older person's usual care team is borne out by evidence demonstrating that this approach to identification of potential study participants is associated with high recruitment rates (Bugeja, Kumar & Banerjee, 1997). Interviews were offered in the home to minimise the impact of travelling on frail older people and their carers. Six older people and one carer agreed to participate in the interviews.

Frailty in Primary Care Study

Background: As people get older they may become frail. Frailty can be described as a set of symptoms which result from a combination of the natural effects of getting older with the impact of developing a number of long term conditions. People who are frail may feel more tired and weak than normal, have trouble getting around, lose weight and feel that they are slowing down. Frailty progresses over a period of 5-15 years and for some people may lead to losing independence, having more hospital admissions and moving to a care home. Previous research has suggested that it may be possible to support older people to manage frailty like any other long term condition. If recognised early, we can provide care and support that may delay frailty so that patients can retain their independence and quality of life. To do this people need effective support at home from health services such as their GP and community and practice nurses. This may include carrying out an assessment of the frail person's needs and working in partnership with them to develop a plan to address these needs which will be individual to them.

The Study: This study aims to explore how frail people can be best supported at home and how GP surgeries and community teams need to work to provide this support. We want to explore if carrying out the assessment and developing a care plan will improve certain measures for patients. These measures are; being independent, better quality of life, less hospital admissions and living in preferred place of care.

Why we would like your help: We are applying to the National Institute for Health Research for funding to carry out this research study. A very important part of the application is the involvement of people and patients in developing plans for the study. We would value your opinion on the study and to understand if the subject and the outcomes seem important to you.

Figure 2.1: Information Sheet for Potential Participants

Thirty-five Community Matrons (CMs) and ten General Practitioners (GPs) were approached to act as Specialist Advisors. CMs were contacted through their local forum and a focus group organised as part of a regular meeting. All thirty-five CMs were invited to attend the focus group and twenty-five participated. GPs were identified through the UK NIHR South West Clinical Research Network as having a particular interest in the care of older people. They were sent a questionnaire based on the conversation guide used for the focus group (Figure 2.2). This method was employed to engage with GPs as, due to time constraints, they would be unlikely to participate in interviews or attend a focus group. Four GPs responded.

1. How do you currently identify and support frail patients?
2. Are there any barriers to delivering effective assessment and care planning in primary/community care?
3. How do you think we could address some of those barriers?
4. Do you think this study would be useful in planning for the future care of our ageing population? If not, what are the topics you would like to see addressed relating to older people living with frailty?

Figure 2.2: Conversation Guide for CM Focus Group

2.5.1 Data Collection

The consultation with the older people and the carer was completed in six individual face-to-face interviews. The duration of the interviews was between 15 and 45 minutes. A semi-structured interview guide (Figure 2.3) was developed and used to facilitate a conversation around the main topics of the proposed study design. In order to ease the people with frailty and their carers at the beginning of the interview, the first

question was always a general question about their experience of living with frailty. After this, the conversation continued with four questions regarding design of the proposed study, maximising recruitment and retention and appropriateness and importance of the proposed outcome measures. The interviews were recorded and permission gained for the recording with the understanding that the data would be safely stored and not identifiable.

1. What are your experiences of frailty?
2. What do you think of our proposed measurements of the study – independence, quality of life, number of hospital admissions, and living in preferred place of care?
3. What information would you want to know if you were participating in the study?
4. How can we best approach people to ask if they would like to participate in the study?
5. Do you have any concerns about this study and if so, what are they?

Prompts:

Why do you say this?

Can you explain this a bit more?

Why do you think this is important?

Figure 2.3: Semi-structured interview guide for older people and carers

Data collection from the CMs was completed in one focus group meeting. A brief background and outline of the proposed study was provided to the focus group participants prior to attending. The focus group discussion was guided by four questions addressing the aim of the consultation round with CMs. The focus group was recorded and notes taken. Permission for the recording was sought with the understanding that the data would be safely stored and not identifiable. After the focus group with CMs a questionnaire with the same three focus group questions and accompanying information sheet with information about the proposed study was sent to General Practitioners (GPs). The GPs were able to return the completed questionnaire via email.

2.5.2 Data Analysis

All data were transcribed and anonymised and original recordings destroyed. After transcription, the data were analysed by the investigators using inductive content analysis (Hsieh & Shannon, 2005). Authors HL and JML completed this process, which involved organising of data through open coding by in-depth and repeated reading and gathering into main categories based on the interview questions. Data were then further grouped, reducing the number of categories by combining similar headings into broader categories. Finally, the third author (BK) reviewed the data to ensure there were coherent patterns and no categories were missed.

2.5.3 Ethical Considerations

Formal ethical approval was not required as part of this involvement process. The NIHR advise that ethical approval is not needed where people are involved in planning or advising on research. In their INVOLVE Guidance they state that:

“Members of the public actively involved in research are acting as **specialist advisors**, providing valuable knowledge and expertise based on their experience of a health condition or public health concern. Therefore ethical approval is not needed for the active involvement element of the research (even when people are recruited via the NHS), where people are involved in planning or advising on research, for example helping to develop a protocol” (NIHR INVOLVE, 2020, p.1).

2.6 Results

Content analysis of the interviews with frail older people and the carer identified a broad category concerning experiences of frailty that were then further analysed to reveal four sub-categories concerning the characteristics of frailty, the challenge of managing multiple long term conditions, organising care and support and worries about losing independence and the links to social isolation and loneliness. Further categories

included advisors' views on content of the proposed intervention, recruitment to a research study and appropriateness and importance of outcome measures.

2.6.1 Experiencing Frailty

Older people and carers described the characteristics of frailty as tiredness, feeling weak and loss of mobility: *"Weakness and everything makes him tired"* (C1). For some, these characteristics were viewed with dismay *"I don't know how this has happened to me...they say I have heart failure, my legs won't work and the nerves in my arm are gone"* (P1). Some participants expressed fear of the impact of frailty on their lives and independence: *"It's very frightening as you get older and can't do as much"* (C1). Others acknowledged the gradual functional deterioration and demonstrated acceptance: *"Getting to the state I am in now comes so gradually you learn to cope with it...you find ways to do things"* (P5). Other people's perceptions of their frailty were discussed by the patients and they expressed satisfaction in the way others view their difficulties and their ability to cope: *"My brother says he couldn't live like I did...but we said to him, if you had the same things wrong you would have to put up with it"* (P1). There is also a feeling that others don't always recognise the impact increasing frailty can have: *"People don't see me as frail...my nephew said to me 'you're not frail, you are as tough as old boots'"* (P4).

Frail older people told us that they struggled with having *"so many things wrong at once"* (P1). They talked about how each long term condition impacted on the others and how this presented challenges for their on-going treatment and care: *"I'm terrified I will need my other hip done because of my heart...and I've had three operations on my spine already"* (P2) *"I take eleven tablets every morning, they give me terrible dizzy spells but I know I need them"* (P2). Strong sub- themes were the importance of determination, coping strategies and developing resilience: *"I can't go out but I use my*

computer to look around the world...you can go anywhere...I watch the surfers on the beach...I don't know of any beach that doesn't have a webcam." (P5). The older people were aware of the impact of their mood on those around them and talked about how the importance of cheerfulness and staying positive: *"I joke with the carers as I don't want them to be miserable, they all love coming here, but I am in so much pain 24/7."* (P1).

All older people and the carer talked about the challenges of navigating and understanding health and social care systems: *"I don't understand the system...I'm not asking for the world."* (P1). They talked about a lack of continuity, which accompanies working with multiple health and social care professionals: *"We've had four different Occupational Therapists for different things; one for the chair, one for the bed, one for the hoist"* (P1). *"If only there was a single number to call"* (C1).

Access to equipment and services was discussed and there was a perceived unfairness associated with charges for care and a perception that previous contributions are not recognised. Carers' time is unpaid and there is little recognition for this contribution when assessments for financial contributions towards care are made: *"If he was in a home it would cost a lot more...it makes you wonder what you've done wrong but my help has kept other help away for a long time."* (C1). Financial burden was highlighted, particularly the cost of care and necessary adaptations to the home. This caused anxiety to both the older people and their carers: *"We have to pay £5000 for a ramp, we just don't have this as we have to pay towards my daughters bills – she moved to this house so we could come and live here...this is not taken into account"* (C1). *"I dread the water bills – that washing machine is never off...we've tried for help but we are above the borderline...we both pay £1,100 per month for our care"* (P2).

All older people and carers were supported by a Community Matron who provides long term case management for frail patients and those with multiple long term conditions. The older people and their carers highlighted the importance of this role and it was felt to have improved coordination of care and integration of services. They particularly appreciated having a knowledgeable single point of contact that is responsive to their needs: *"S.... is the best medic I have ever come across...whenever I ask her a question she gives me the right answer...anything, no matter what I ask"* (P4). *"If I need help I ring K.... first of all...I seem to feel so comfortable with her...I know she will do her best for me"* (P5). Another key aspect of the role is that of coordination of services and care: *"We only have to ask C..... and she says 'Well what about so and so'...by having her come in it all got put together and treated like a person not just a name."*(C1).

Frail older people placed high importance on staying independent and remaining in the home for as long as possible: *"We want to stay at home...we really don't want to go into a home"* (P2). They expressed dismay at how they are viewed by wider society and the loss of control over their own lives they have experienced: *"People don't tell me the things that are going to happen"* (P4). They expressed frustration when care-givers do not respect their independence and may schedule visits which then limit this independence further: *"Timing of district nursing visits is important...they come and do my legs every day...one day I was able to go out with my friend but they (the district nurses) could have come at any time and that's a day out of my life when I've had no social contact."* (P4). This links to the need to remain engaged with society and playing an active role within it: *"I'm fed up with looking at the walls...I feel like a prisoner...I'd like to go out and see the other world"* (P1). This statement was reinforced by the

patient's carer who stated *"They forget older people like to go out...four walls are very hard to take"*. (C1).

A strong sub-category was the subject of social isolation which accompanied increasing frailty and loss of independence. All older people and the carer highlighted this as an important issue which impacted on quality of life. Several of the patients talked about how they had tried to retain their links to society and how their attempts eventually fail: *"When I had to give up my car I bought a scooter...I used it to go out regularly, but then it got that it was getting too much for me...that was my independence gone."* (P3). All patients were housebound and they expressed feelings of frustration and sadness caused by loneliness: *"The only time we get out is to see a specialist"* (P2). *"The winter seemed endless to me...like today I put on my jacket to sit outside...I used to do my own garden...I want to get outside and do my tubs."* (P5).

2.6.2 Views on the content of the proposed intervention

Patient and Carer Perspectives

This part of the consultation involved gaining the perspectives of older people, carers and clinicians on the content of the proposed intervention. The intervention is a nurse-led holistic assessment and care planning process which would identify the needs of older people living with frailty and work in partnership with them to develop a care plan to address these needs with an overall aim of maximising independence and quality of life. All older people and carers thought that the proposed study topic was an important one particularly given the ageing population and increasing numbers of older people needing care and support. Some expressed that the needs of older people can be ignored and were pleased to see this issue was being prioritised: *"You don't change inside...I might be 72 but I don't feel 72...and there will be many more of us."* (P1). *"No, it's nice to know someone is thinking about older people who are frail"* (C1).

When asked about the importance of the intervention to them, the older people talked about having one person who led coordination of the complex care plan and was easily accessible. The carer also said that they would value “...*someone to fall back on...*” (C1), information on who to call for help and what to do in different circumstances: “*There should be a booklet explaining how to do things...who to approach for different things and who to approach in different circumstances...*” (C1). Once again the issue of independence was emphasised but with the need for adequate support to retain that independence.

Clinicians’ Perspectives

Data collected from GPs and CMs revealed that they currently identified frail people using a screening tool or by clinical assessment, or they had no systematic identification method. Current barriers to effective frailty management in community care were discussed and main themes identified were; an increased focus on more acute care in the community with less time on the caseload to complete full assessments and plan care, the existence of a “*firefighting culture*” (CM4) with less time to be proactive and preventative. Concerns were expressed about the current skills level in primary care with a lack of knowledge about frailty and its management. Some suggested enablers to address these barriers were to streamline referral processes and assessment, to ensure the essentials of assessment were covered and then shared to avoid duplication. The focus of the proposed study should be to determine the ‘*essentials of a Community Geriatric Assessment*’ (GP4) that are feasible in primary care and will make a difference to patients. Coordination and continuity of care was seen as vital and time to develop a relationship with the patient and carer is needed.

2.6.3 Views on Recruitment

The older people and carers addressed some important considerations for recruitment to the study involving participants who are frail. When asked about measures that could support recruitment to the proposed study and how best to approach frail older people to gain their engagement, opinions were varied. Some older people and the carer felt it would be best to approach through a known primary care clinicians rather than receiving a letter in the post: *"If you got a letter you might think oh that's something official, what's that about, whereas my Community Matron coming in to explain to us, I was like 'oh yeah that's no problem'"* (C1). Others commented that they would be happy to receive an initial invitation to participate in the post, some were not concerned about which way they were contacted: *"A letter or a phone call...whichever is easiest"* (P5). There were varying opinions on the information leaflet that introduced the study, some felt it was helpful in understanding the topic and as background to the proposed study; one patient thought it was not helpful

2.6.4 Views on Outcome Measures.

When asked about the outcome measures that were important for the study, quality of life and staying out of hospital were the most important outcomes for the older people and the carer: *"It's important for us...he doesn't want to go into hospital again and he doesn't want resuscitating, we've got the forms for all that..."* (C1). *"Anything that keeps old people in their own homes can only be good."* (P5). Several older people talked about how quality of life is very individual and could be achieved with relatively simple interventions.

Whilst 'hard' outcomes such as prevention of admission to hospital, reduction in general practice contacts etc. were seen as important, all advisors stressed the

importance of meaningful outcomes that led to improved quality of life and functional independence.

2.7 Discussion

The importance of early involvement of older people who were also patients, their carers and other stakeholders in designing and planning research studies has been reinforced by this consultation. It has demonstrated that older people and carers valued the research topic and gave important insights into how to maximise recruitment into the trial. The proposed methodology has been designed to answer some of the questions and issues raised by older people, carers and clinicians and the research protocol has been adapted to ensure patients are approached in a sensitive way that will maximise recruitment to the trial based on the data from this consultation.

Valuable insight was gained into the lived experience of older people living with frailty and their carers. The theme detailing the characteristics of frailty and how the clinical syndrome is experienced in reality is borne out by earlier research (Britain Thinks, 2015). This found that the term frailty isn't part of older people's vocabulary when describing themselves and their lives; but that older people describe frailty and wellbeing in terms of everyday tasks and how it feels if these tasks start to become difficult. Older people within the consultation emphasised how it felt to them to struggle with activities of daily living and the feelings of frustration and sadness they experienced, but were also keen to show their resilience and coping strategies when presented with these challenges. This has highlighted the importance of the researchers in explaining frailty to participants in terms of its effect on health and wellbeing and to focus on support to maintain independence.

A strong theme that had not been considered in the original research proposal was the older peoples' anxieties regarding losing independence and the links to social isolation and loneliness. This has been acknowledged in the frailty literature in recent times with social isolation becoming increasingly recognised as an independent risk factor for frailty (Herrera-Badilla *et al.*, 2015). Guidance published by the National Institute for Clinical Excellence (NICE) on prevention of frailty and dementia emphasises that age-related physiological changes can be impacted by personal, social and environmental circumstances which may limit social interaction (National Institute for Health and Care Excellence, 2015). In addition, there is emerging evidence on the importance of psychosocial risk factors throughout life such as loneliness, isolation and depression. These factors may reduce resilience to disease onset and progression. NICE highlights that psychosocial factors may be as important as physical factors in reducing the risk of dementia and frailty. Changes will be made to the proposed study design to include the risk factors of social isolation and loneliness in the development of the assessment and care planning tool.

Using the feedback from the participants, recruitment to the trial will be led by the General Practice who will send out the initial recruitment letter and participant information sheet to ensure the potential participants can ask questions and gain support from their primary care clinicians. This is aimed at addressing any potential barriers to recruitment and ensuring targets for recruitment are met.

It was encouraging to see that the proposed outcome measures for the study were seen as important and relevant to the patients and carers. Most importance was placed on remaining at home with a reasonable quality of life. It is recognised that measuring quality of life in older people who live with multiple complex conditions can be challenging and that many validated tools are not tested in populations of older people

(Diener, 2012; Neve *et al.*, 2013; Steptoe, Deaton & Stone, 2015). The proposed study design has been altered to consider specific tools which measure quality of life and overall well-being in older people such as the SF-36 (Ware & Gandek, 1998) which has evidence for measurement of emotional health and mood in older people (Akpan *et al.*, 2018). The advisors all stressed the importance of a person-centred approach with outcomes and goals based on individual patient preferences and needs. The research team have considered this when designing study outcome measures and included measurement of quality of life, functional independence and remaining in preferred place of care.

The major limitation of the consultation was the small numbers of patients and carers who participated; however, there were larger numbers of clinicians. This combination did provide a rich source of data, which enabled the study protocol to be reviewed and improved. This ensures that the design meets the aims and objectives of the study and that we will be able to implement appropriate measures to maximise recruitment of participants.

2.8 Conclusion

Completion of this PPI consultation has reinforced the importance of early involvement of patients and the public in study design. It enables researchers to understand the topic from the patient's perspective and to ensure relevance and importance. This should, in turn, enable high quality study design and relevance to the wider population. This is particularly important when carrying out research involving vulnerable, hard to reach groups such as older people and their carers who live with frailty. In relation to this proposed study, one of the challenges is related to recruiting adequate participants who are moderately or severely frail. Our PPI work has enabled us to test some of the proposed methods including face-to-face interviews and focus groups but we may

need to consider more novel ways in which frail older people can be engaged in consultation work. Despite these challenges, we would strongly advocate the benefits of PPI work in research design.

Chapter 3: Study Design

3.1 Chapter introduction

Informed by the PPI consultation described in Chapter Two and in line with the Medical Research Council guidance on developing and evaluating complex interventions (Cathain *et al.*, 2019; Craig *et al.*, 2008), it was clear that the use of one research method would not be effective in developing the content of the intervention and determining the feasibility of conducting a trial in primary care. Survey methods with the aim of achieving consensus would enable development of the intervention and qualitative research would enable a deeper exploration of clinicians and participants' experiences of participating in a trial. Consequently, a mixed-methods design comprising of three phases, including a Delphi survey, feasibility RCT and embedded qualitative study, was agreed on and further developed.

This chapter explores the theoretical conceptual paradigms for mixed-methods research and describes, and justifies, the chosen study methods. It demonstrates how each method contributes to meeting the research aims and objectives and how the mixed-methods approach contributes to a holistic approach to integrating and interpreting findings. This enables more comprehensive conclusions to be drawn when evaluating complex healthcare interventions (Cathain *et al.*, 2019). In this case, this includes exploring how this feasibility trial will inform the conduct of a full trial, involving stakeholders in iterative intervention development and providing intelligence to support the implementation of the intervention in real world clinical practice.

3.2 Mixed-methods research

Plano Clark and Ivankova (2016) describe mixed-methods research as

“...the intentional integration of qualitative and quantitative research methods to best address a problem”. (p.4)

Since the 1980s, mixing research methods has become increasingly accepted as a legitimate approach, notwithstanding differing views on the integration of quantitative and qualitative methods (Greene, 2008; Johnson, Onwuegbuzie & Turner, 2007). Greenhalgh and Papoutsis (2018) argue that many evaluation studies testing complex interventions fail to embrace the concept of complexity fully. They suggest that complex health systems have blurred boundaries where clinicians operate internal rules and adapt and evolve those systems iteratively. It can be argued that randomised controlled trials alone will not fully answer questions as much of real life healthcare cannot be controlled for (Greenhalgh & Papoutsis, 2018). Therefore, more in-depth, mixed-methods approaches are needed to explore the dynamic nature of testing feasibility of an intervention and its implementation. The original Medical Research Council Framework for the development and testing of complex interventions (Craig *et al.*, 2008) was updated in 2015 (Moore *et al.*, 2015) and in 2019 (Cathain *et al.*, 2019) and emphasised the need for more mixed-methods and process-based studies to explore the challenges of non-linearity and iterative local adaptations.

The HAPPI study sought to apply the principles of mixed-methods research throughout the research process using an integrated approach to conceptualising and interpreting findings. To ensure this approach was incorporated at each stage of the study, it was necessary to appraise the underpinning philosophical principles of mixed methods research and their application. This theoretical paradigm will be explored in section 3.3.

3.3 The theoretical paradigm

Mixing research methods poses a dilemma in that the underpinning philosophies of quantitative and qualitative research appear to be at odds with each other. The traditional philosophical foundation for quantitative research is positivism, which states

that all reliable knowledge can be verified by scientific enquiry. This scientific, experimental method was introduced by August Comte (1798–1857), who is regarded as the first philosopher of modern science (Crotty, 1998). In the early 19th century philosophers such as Karl Popper introduced the philosophy of post-positivism, which, while continuing to value objectivity, recognised that researchers' values and background can influence their research and that this potential source of bias should be acknowledged and managed (Popper, 1959). The postpositive movement set the context for the development of qualitative methodologies and for the mixing of research methods in the 1980s (Giddings & Grant, 2007). Qualitative research is rooted in the paradigm of constructivism where the study aims to describe multiple realities, including that of the researcher, to interpret meaning and contexts from the experiences of individuals (Lincoln & Guba, 1985).

Some writers claim there is no need for tangible connections between specific philosophies and certain research methods (Cook, 1979; Greene, Caracelli & Graham, 1989). In order to move the knowledge base forward, Greenhalgh proposed a break from traditional paradigms and questioned “prevailing assumptions and methodological rules” (Greenhalgh, 2013, p.92). The integration of research methods in mixed-methods research and their founding conventions can be challenging as the researcher may be operating from or attempting to combine differing paradigms within one study. Furthermore, the investigator will operate within his or her personal and professional context. This reflexivity is acknowledged and viewed as an essential and valued contribution in qualitative research ontology (Giddings & Grant, 2007). The concept of reflexivity is given less importance in quantitative methods where objectivity is prized (Dodgson, 2019). Reflexivity describes the perspectives and interconnecting

relationships between the researcher and participants and the influences the researcher's personal standpoint and values may have on the research (Berger, 2013).

The author of this thesis is a nurse and, as such, draws on both quantitative and qualitative research data to inform clinical practice. It has been argued that nursing can be considered both an art and a science (Jasmine, 2009) with its roots in caring, whilst also acknowledging the need for scientific, evidence based research on which to base practice. In the HAPPI study, the use of quantitative data may offer a high level of accuracy and objectivity of results, whereas qualitative data can provide an effective way of exploring attitudes, feelings and behaviours in depth and detail.

In order to provide clarity and transparency, I acknowledged my personal position in relation to the study and the ethical challenges which might arise. As a nurse and a researcher, I occupied a dual role where my clinical background and the desire to support and respond to participants in a caring capacity could be at odds with the objectivity required as a Chief Investigator and an interviewer in the qualitative phase. There was also the potential for blurring of role boundaries, where participants might view me as a clinician rather than an independent researcher. During supervision sessions, ethical and practical issues were reviewed and discussed so that there was a constant awareness of the tension between the privileged relationship with and access to participants and maintaining my responsibility for rigour in the conduct of the study (Hiller & Vears, 2016).

In designing the study, ultimately, a pragmatic stance was taken in order to value the practicality of a wide range of designs and their applicability to the world of complex healthcare evaluation. There was an awareness of underpinning ideologies so that in mixing methods, they were not at odds and that each method and their results were given equal weighting, so avoiding domination of one method over the others. If there

was a disparity in findings across methods, then, as a feasibility study, this provided the opportunity to refocus the research questions and original research assumptions. Lather argues for “disjunctive affirmation” where paradigm disagreement is neither a “cause for war nor requires reconciliation” (Lather, 2006, p.52). Maxwell (2011, p.28) suggested adopting a “bricolage” approach where philosophies can be viewed as practical tools and the researcher can assemble their own toolkit to fit their personal perspective and the purpose of their research. This justification aligns fully with the aims and objectives of this study.

3.4 Study methods

A holistic picture of findings from both qualitative and quantitative elements of a study can be achieved by the integration of statistical and thematic data analytic techniques. This approach can allow a deeper insight by aiming to achieve complementarity, where quantitative and qualitative methods are combined leading to a more complete and multifaceted understanding of a phenomenon (Greene, Caracelli & Graham, 1989). This is particularly relevant when testing the feasibility of a complex intervention where the processes and the outcomes of the intervention and its implementation are explored. In mixed-methods research, integration of methods and findings to complete the whole picture should be the aim; the process by which this was achieved will now be presented.

The study was designed using sequential timing. Initial quantitative data were gained using e-Delphi survey methods to develop the content of the intervention then further quantitative data collected from results of the fRCT, which tested implementation. Embedded within the trial, qualitative data were used to understand experiences of the intervention and to explain its implementation. Mixing of the data occurred when results were interpreted together to obtain the holistic picture. There are strengths and

limitations of this approach (Plano Clark & Ivankova, 2016). Sequential timing is convenient for the planning and organising of a study. It allows for exploration of the quantitative results in more detail and aligns with the recommendations for evaluating complex interventions (Moore *et al.*, 2015). However, a sequential design can prove lengthy to complete and, therefore, the qualitative study was embedded within the fRCT to fit within the timeframe of the NIHR fellowship. Figure (3.1) details the research activities undertaken in sequential format within a complementarity framework.

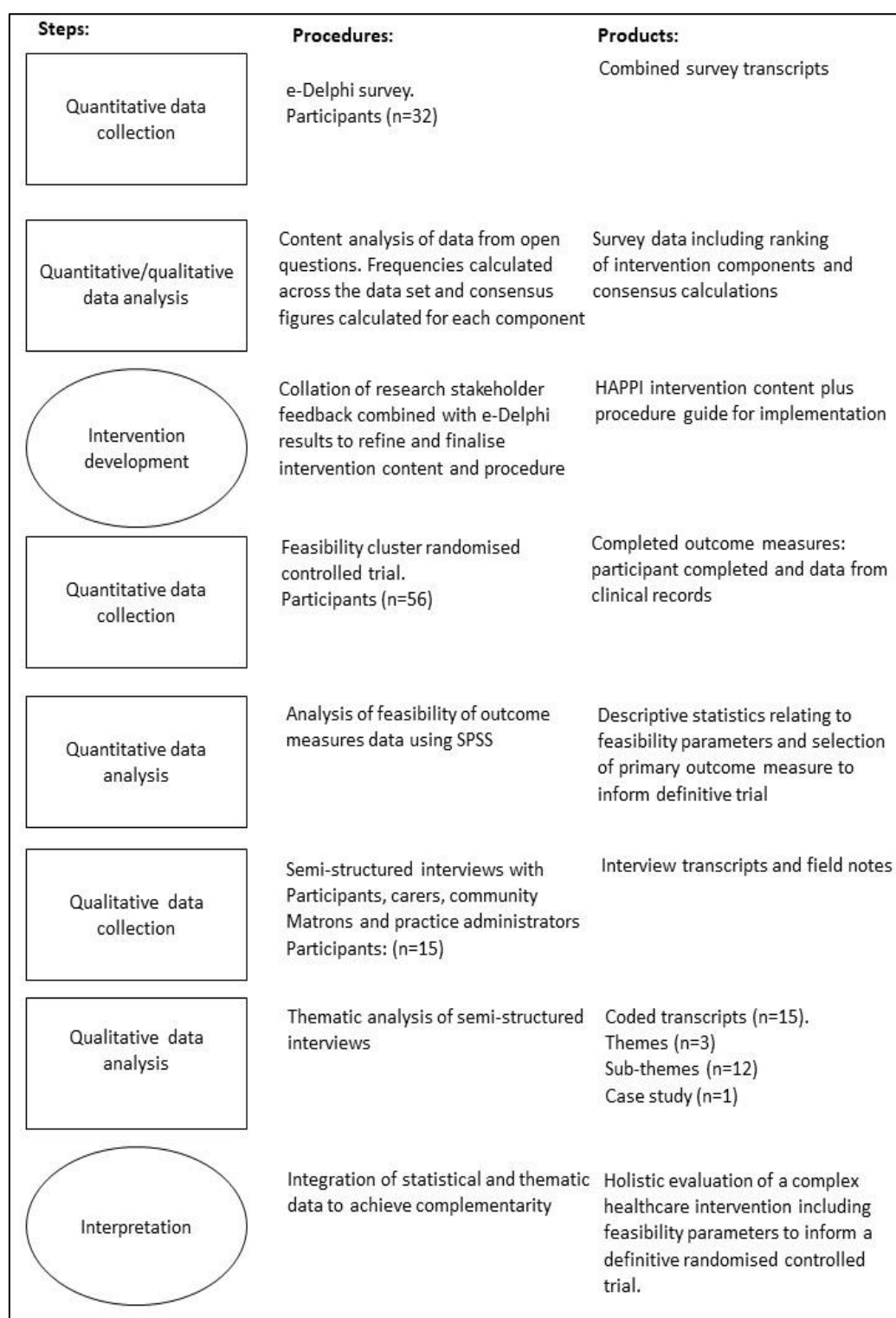


Figure 3.1: Mixed-methods research activities undertaken

The primary aim of the HAPPI study was to determine the feasibility of delivering a nurse-led assessment and care planning intervention in primary care to older people with frailty and to test potential trial methods to inform the design of a definitive randomised controlled trial (RCT). Specific objectives were achieved within the three phases of the study using quantitative and qualitative methods. Development of the intervention was completed in the first phase of the study using an e-Delphi survey and research stakeholder involvement. The fRCT enabled assessment of feasibility of the intervention and delivery of the trial including compliance with the HAPPI intervention, verification of proposed outcome measures and their collection and determining achievable targets for recruitment and follow-up. Further objectives were met within the embedded qualitative study including determining acceptability of the intervention to patients, carers and clinicians in primary care, assessment of barriers to delivery of the HAPPI intervention and acceptability of trial processes and collection of outcome measures to participants. This mixed-methods research approach was thus designed to achieve complementarity and provide a structure for the evaluation of a complex intervention examining all aspects of its development in addition to the feasibility of its implementation.

Subsequent chapters of this thesis present the methods, findings and discussion of the findings for each phase of the study.

Chapter 4: Development of the Intervention

4.1 Introduction

Building on the information from the PPI consultation, in the next phase of the study, an e-Delphi survey was conducted to gain consensus on the detailed content of the HAPPI intervention with an expert panel made up of specialist nurses for older people, community and primary care. In order to ensure wider stakeholder involvement, the results of the survey were then shared with a group of older people, carers and senior clinicians to verify and confirm the content and delivery of the intervention. This chapter describes the methods and results of the e-Delphi survey and the research stakeholder group leading to the finalisation of the intervention to be tested in the fRCT. The content below has been submitted as a manuscript for publication to the International Journal of Older Peoples Nursing and the format of this chapter reflects the submitted manuscript which is currently under review. An estimated percentage of contribution (%) of each author is as follows: Lyndon, H. (85%), Latour, J.M. (5%), Marsden, J. (5%), Kent, B. (5%). The percentages of contributions have been agreed among all authors.

Designing a Nurse-led Assessment and Care Planning Intervention to Support Frail Older People in Primary Care: An e-Delphi Study.

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4.2 Abstract

Aim: The aim of this study was to obtain expert consensus on important and feasible components of a primary care, nurse-led, comprehensive geriatric assessment (CGA)-based approach.

Background: To meet the challenge of a growing frail, older population, there is a need to provide proactive care using a person-centred, CGA-based approach in primary care. Currently, there is no evidence for which components of a CGA can be effectively delivered in this healthcare setting.

Methods: A three-round e-Delphi survey was conducted with an expert panel of 75 UK specialist older people and primary healthcare nurses. In round one, experts gave their opinions on the important components of a CGA-based approach. In round two the experts rated the components for importance and feasibility. In round three, in order to achieve consensus, experts re-rated the components based on group opinion. Data were analysed using thematic analysis of the content in round one and descriptive statistics in later rounds to indicate convergence of opinion and, ultimately, consensus.

Findings: In round one, 36 CGA components were identified by the experts and based on a literature review. These were clustered into six domains: frameworks/care structures; home/family/safety assessment; personalised care and support planning; long-term condition management; physical health assessment; mental health assessment. In rounds two and three rating scores for importance were high across all domains, with lower scores for feasibility. The 36 components achieved consensus on importance, but only 11 out of the 36 components reached consensus on feasibility.

Conclusions: Of the 36 identified CGA-based components, 11 were deemed to be feasible in delivering optimised person-centred care to frail older people in community

settings. Results of the study will inform the development of a nurse-led CGA-based approach which will be evaluated within a randomised controlled trial.

Keywords: older people; frailty, comprehensive geriatric assessment; care planning; intervention; primary care.

4.3 Background.

Frailty is a clinical syndrome associated with ageing, which develops through cumulative cellular damage over the life course and leads to progressive disability and loss of independence (Clegg *et al.*, 2013). Frailty assessment has been biomedical in nature, focusing on the diagnosis and treatment of the clinical syndrome (Hoogendijk *et al.*, 2019). However, this approach fails to capture individuals' differences and can cause clinicians to neglect peoples' abilities to participate in their own care and support (Rahman, 2018). An asset-based model of assessment and support takes a more holistic, multidimensional approach to managing frailty and has been promoted by the World Health Organisation as a means of preserving function, personhood and independence (World Health Organization, 2015).

In the UK and other countries, assessment of frailty is most commonly undertaken in acute hospitals using a Comprehensive Geriatric Assessment (CGA) which is led by a geriatrician (Clegg *et al.*, 2013). This assessment and care planning process is acknowledged as the gold standard approach for the management and prevention of deterioration in frailty (Gladman, 2016). It is a multidimensional, interdisciplinary diagnostic process to determine the medical, psychological and functional capabilities of a frail older person in order to develop an individualised care plan for treatment and long-term follow up in partnership with the patient and their families (Ellis *et al.*, 2011). The British Geriatrics Society (BGS) have suggested an alternative to hospital-based, geriatrician-led CGA, proposing that, in primary care, a 'holistic review' by a general practitioner (GP) or specialist nurse may enable more frail older people to access services out of hospital (Turner & Clegg, 2014). Unfortunately, there is no evidence to indicate that the acute hospital CGA is immediately transferable and achievable, or

that primary care clinicians (including nurses) possess the specialist skills and knowledge to deliver this care model.

To support the movement of CGA from secondary to primary care, the BGS has published a Comprehensive Geriatric Assessment Toolkit for Primary Care Practitioners (Turner *et al.*, 2019). This toolkit is 48 pages in length and takes a minimum of two hours to complete. The BGS themselves acknowledge that its completion by GPs may not be possible due to short appointment times and lack of capacity in the current UK model of primary care. Additionally, its full completion may not ensure a person-centred approach as not all components may be appropriate for all frail older people. Consequently, there remains a need for a more holistic, flexible approach that can be delivered by primary care professionals other than GPs and adapted for the individual and their needs, whilst being practical to implement. In addition, evaluation of the role of nurses in leading this care model is required

Beswick *et al* (2008) found that the delivery of complex interventions (based on CGA) for older people at home can reduce care home and hospital admissions and falls. A systematic review investigating the implementation of one primary care CGA-based approach noted a lack of an agreed implementation model and concerns of workforce capacity in UK primary care (Craig *et al.*, 2015). Another review attempted to identify approaches to CGA in primary care and found several in existence. However, the review identified the need for more research into what is feasible for large numbers of the population (Morley *et al.*, 2017). With growing numbers of older, frail people, this topic has gained interest in the UK and abroad. How best to deliver CGA to frail older people in a range of healthcare settings was one of the top ten research priorities identified by the UK priority setting organisation (James Lind Alliance, 2018).

The BGS issued a Position Statement on Primary Care for Older People (British Geriatrics Society, 2018), which proposes that there should be a multi-professional approach and pointed to some evidence that nurses and allied health professionals can successfully lead and input into the assessment and care planning process (Schadewaldt *et al.*, 2013). However, the nursing contribution to frailty management is poorly developed, with studies assessing nurse-led approaches showing mixed results (Bleijenberg *et al.*, 2017a; Schein *et al.*, 2005; Stijnen *et al.*, 2014a; Stijnen *et al.*, 2014b; Taube *et al.*, 2018).

Whilst a CGA-based approach may be appropriate for primary care delivery, the practicalities of its implementation require further exploration, including which components can and should be led by nurses rather than doctors. The use of alternative clinicians to lead CGA may, in itself, provide additional capacity to support more frail older people closer to home.

4.4 Aim

To meet the challenges of an increasingly frail, older population, there is a need to provide proactive, holistic, person-centred care led by nurses that is clinically effective. However, it is not yet clear what the content of that approach should be or if a nurse-led model is feasible. Therefore, the aim of this study was to identify and reach consensus on components of a primary care, nurse-led CGA-based care delivery model.

4.5 Methods

4.5.1 The e-Delphi process

The Delphi method is an iterative process comprised of repeated rounds of voting and is effective for determining expert group consensus where there is little or no definitive

evidence and where opinion is important (Babak *et al.*, 2019). This Delphi survey was conducted as the first phase of a mixed-methods feasibility study to develop and test a nurse-led assessment and care planning approach for frail older people in primary care.

Methods and results are reported in line with the “Guidance on Conducting and Reporting Delphi Studies” (CREDES) (Jünger *et al.*, 2017) which promotes consistency and quality in conducting Delphi studies. Figure 1 summarises the Delphi process. In order to provide rigour and transparency in methods, study procedures were planned in detail and piloted whenever possible.

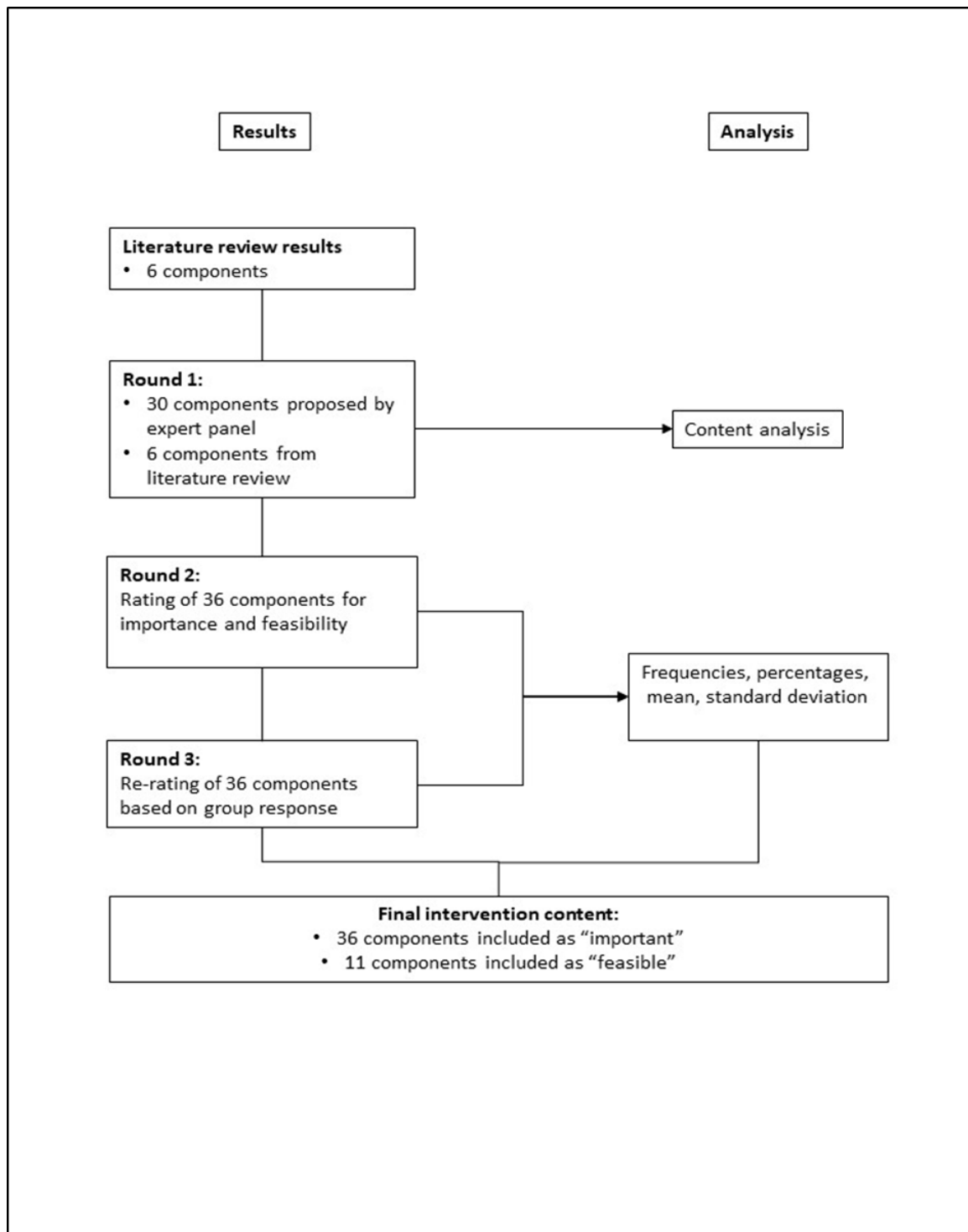


Figure 4.1: Delphi methods and results

4.5.2 Survey Preparation

The study consisted of a three-round electronic Delphi (e-Delphi) method, which was conducted between September 2017 and January 2018. The study followed a modified Delphi technique (Foth *et al.*, 2016) using literature review, opinion and the judgment of experts. It aimed to reach consensus on an issue from an expert panel (Keeney, Hasson & McKenna, 2011). The use of an electronic survey provided advantages over paper versions, including high quality data collection, ease and speed of administration, direct communication with individual panel members, and rapid collation of feedback allowing data collection to be undertaken in a limited time period (Gill *et al.*, 2013). Ethical approval was provided by the University of Plymouth Faculty Research Ethics and Integrity Committee (Reference Number: 18/19-1027).

4.5.3 Literature review

A review of the literature was completed to identify what was already known regarding the content of nurse-led CGA-based approaches in primary care. A search of PubMed and CINAHL English language journals from 1990 to 2017 was undertaken to identify articles on the topic. The search strategy combined headings and keywords for “comprehensive geriatric assessment”, “CGA”, “primary care”, “community care”, “nursing assessment”, “care plan” “frail”, “older people”. Information on components of an intervention were extracted and listed. This information was not shared with the expert panel in round one so as not to influence panel members’ judgements and prevent bias in the first open-ended opinion round.

4.5.4 Development of the e-Delphi surveys

The round one survey was designed by three research team members. Subsequently, the survey was piloted with two clinicians for ease of use, understanding of content and amendments were made prior to the first round. The round one survey began with

information on the purpose of the study and an informed consent form. Consent included panel members agreeing to the use of email addresses to contact with subsequent survey rounds. Initial questions related to the demographic characteristics of the experts including years qualified as a nurse, specialist area of practice and any specialist qualifications. There was one open-ended question; “Please give your ideas about the components of a CGA intervention that you think are important and will improve clinical outcomes for frail older people in a primary/community setting. Please list as many as you can for example; multidisciplinary team involvement, agreeing a plan of care and support, medication review, environmental assessment, etc.”

The round two survey consisted of 36 components of CGA suggested by the panel members and the results of the literature review. Panel members were asked to rate each component on two issues; importance and feasibility. Importance was rated on a five-point Likert scale ranging from one is ‘not important at all’ to five is ‘extremely important’. The feasibility scale was a five-point Likert scale ranging from one is “not feasible” to five is “extremely feasible”. The last question in this survey was an open-ended question asking if there were any missing components that could be included in the next round.

The round three survey consisted of 36 components. The aggregated results (frequency and percentage) for each component from round two were presented back to the panel along with the same rating scales so that panel members had the opportunity to re-rate based on the group response in round two.

4.5.5 The expert panel

The research team aimed to recruit at least 20 expert panel members from across the country in order have a national panel with expertise in the care of older people in primary care. Expert nurses were contacted through the British Geriatrics Society

Nurses Council, the Royal College of Nursing Older Peoples Forum Steering Committee and the National Health Service (NHS) National Community/Primary Care Nurses Forum. Participating organisations were asked to provide letters of approval and confirm that they would share the survey with their members. Panel members were sent an invitation to participate and a participant information sheet. The surveys were administered via an online survey platform, "SurveyMonkey". They were directed to SurveyMonkey (<http://www.surveymonkey.com/>) with a URL specific to this survey. Panel members were asked to confirm consent through the completion of an online consent form as part of the first round survey.

4.5.6 Confidentiality and Anonymity

Panel members were assured of anonymity in the participant information sheet. Internet protocol addresses were used to contact panel members who could not be identified in the process and individual responses were unknown to other panel members.

4.5.7 Statistical analysis

Statistical analysis and definition of consensus were planned and agreed prior to data collection. Panel members' demographic characteristics were reported by descriptive statistics; frequencies and percentages. Data from the open-ended question in round one was qualitative and analysed using content analysis (Hasson, Keeney & McKenna, 2000). In round two, frequencies and percentages for all ranking scales were calculated prior to being presented back to the panel in round three. In addition to frequencies being derived, means and standard deviations for ranking scores were calculated to assess convergence of opinions from round two to round three. Final consensus figures (percentage consensus for each component) were calculated for reporting after round three.

4.5.8 Response rate

There is no specific guidance available for acceptable response rates in Delphi studies. Some Delphi studies relating specifically to older people's care have not reported response rates (Goldberg *et al.*, 2016; Mahoney *et al.*, 2017). However, others have reported between 75% (Rodríguez-Mañas *et al.*, 2013) and 92% (Jeffs *et al.*, 2017). Due to the iterative process of Delphi studies there is the potential for panel members to withdraw after subsequent rounds, which can lead to response bias if attrition is significant (Evans, 1997). Some authors recommend that a 70% response rate is necessary for each round to maintain rigour (Sumison, 1998). In this study, a response rate of 70% was anticipated to the rounds two and three. In order to encourage consensus, three reminders to complete the survey were sent to the panel members.

4.5.9 Definition of consensus

An a priori definition of consensus was agreed by the research team (Jünger *et al.*, 2017). For this to be achieved, 75% expert panel agreement that a component met the criteria of "very important" or "extremely important" and "very feasible" or "extremely feasible" was required at round three.

4.6 Results

Panel members who were invited to participate were volunteer experienced nurses (n=75) who, at the time of the e-Delphi, worked with older people in primary and community healthcare settings. Thirty-three of the panel members responded to the first round survey and one respondent withdrew from future rounds. Response rate to the round two survey was 72% (23 out of 32) and the round three survey achieved a 91% response rate (21 out of 23).

4.6.1 e-Delphi round one

Content analysis generated an initial 35 components suggested by the expert panel. These were aggregated into 30 components and grouped into six domains and ranked by number of responses. The domains were; (1) frameworks/care structures; (2) home/family/safety assessment; (3) personalised care and support planning; (4) long-term condition management; (5) physical health assessment; (6) mental health assessment.

Six additional components were incorporated from the literature review (Table 4.1). These were a system for information gathering, a shared care record, listening to the patient's story as part of personalised care and support planning, assessment of pain, assessment of vision, hearing and dentition and assessment of bladder and bowel function. The combination of these components and those from the expert panel opinion resulted in a round two survey of 36 components clustered in the six domains.

Table 4.1: Components identified in round one

	Components	Number of Responses
Frameworks/care structures		
1	Multi-disciplinary team discussion/review	8
2	Coordinated multidimensional assessment and care with an identified lead clinician/case manager	5
3	A competent, well trained workforce who can deliver an assessment and care planning intervention	3
4	A timely response to crises	1
5	A system for data/information gathering e.g. past medical history, social circumstances, family history	*
6	A shared care record	*
Home/family/safety assessments		
7	Environmental assessment including housing and equipment aimed at maximising independence	11
8	Assessment of social support including financial concerns, benefits entitlement, social isolation	8
9	Assessment of functional ability and activities of daily living including reablement potential	5
10	Assessment of falls risk	3
11	Assessment of carer's needs	3
12	Determining spiritual needs and support systems	1
13	Exploring opportunities for employment/education/hobbies	1
Personalised Care and Support Planning		
14	Agreeing and formulating a plan together based on shared decision making and the preferences of the individual: working the partnership	10
15	Safeguarding this contract by documenting it in a co-created care or support plan: personalised care and support planning	10
16	Monitoring response to the care and support plan	10
17	Review and revising of the care and support plan	10
18	Empowerment and self-management and enabling behavioural change	6
19	Determining advance care preferences	4
20	Establishing the patient's personal goals and where support is needed (person centred care)	4
21	Assessment of resilience and coping mechanisms – an asset based approach	3
22	Escalation/contingency planning: actions for when the patient's condition deteriorates	2
23	Assessment of patient's ability to actively participate in care and planning	2
24	Establishing an individual's narrative by active listening/appreciative enquiry	*
Long Term Condition Management		
25	Medication review including ability to self-administer, concordance and de-prescribing	10
25	Advanced clinical assessment skills – physical examination and ordering investigations	6
27	Problem/deficit identification	3
28	Optimising management of long term conditions/multimorbidity	1
Physical Health Assessments		
29	Assessment for the presence and severity of frailty	2
30	Assessment of nutritional status including hydration	1

	Components	Number of Responses
31	Sexual health assessment	1
32	Assessment of pain	*
33	Assessment of vision, hearing and dentition	*
34	Assessment of bladder and bowel function	*
	Mental Health Assessments	
35	Assessment of cognition	6
36	Assessment of mood and psychological well-being	6

* Component taken from literature review

4.6.2 e-Delphi round two

In round two, the 36 components were presented to the panel members for ranking on importance and feasibility. Full results with frequencies, percentages, mean scores and standard deviations for all components in rounds two are presented in Supplementary Information 1 (Appendix 2). When analysed in the six domains, mean scores for importance were high across all components and lower for feasibility with the exception of the frameworks/care structures domain which were high for both importance (mean 4.8; SD 0.06) and feasibility (mean 4.8; SD 0.06). All other domains had mean scores ranging from 4.4 (SD 0.50) to 4.59 (SD 0.11) for importance and between 3.47 (SD 0.25) and 4.59 (SD 0.33) for feasibility. No additional components were suggested by panel members.

4.6.3 e-Delphi Round three

Results with frequencies, percentages, mean scores and standard deviations for all components in round three are presented in Supplementary Information 2 (Appendix 3). Domain mean scores for both rounds are visualised in Figures 4.2a and 4.2b to demonstrate increasing mean scores and convergence of opinion across the rounds.

Figure 4.2a: Domain mean scores for importance (rounds two and three)

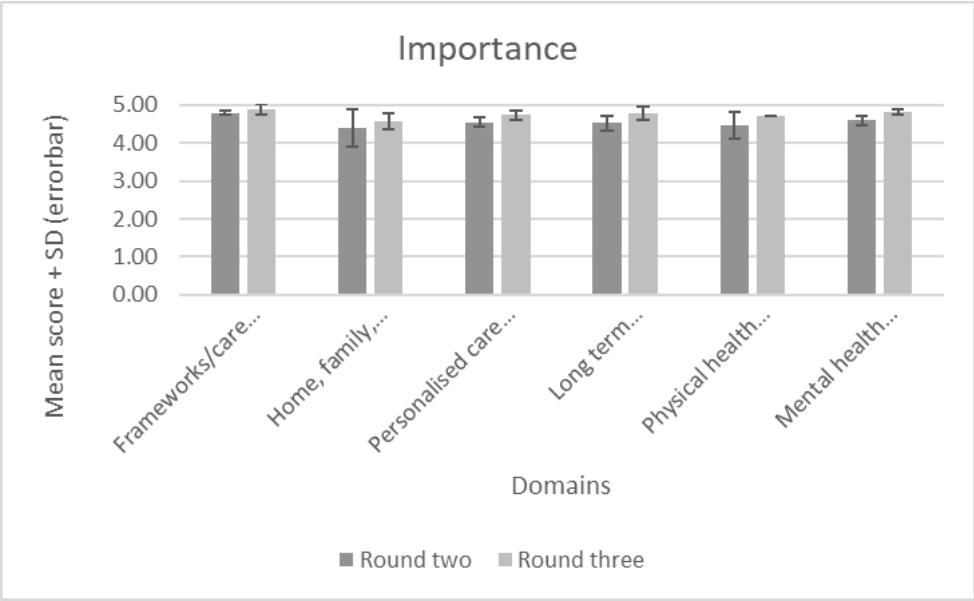
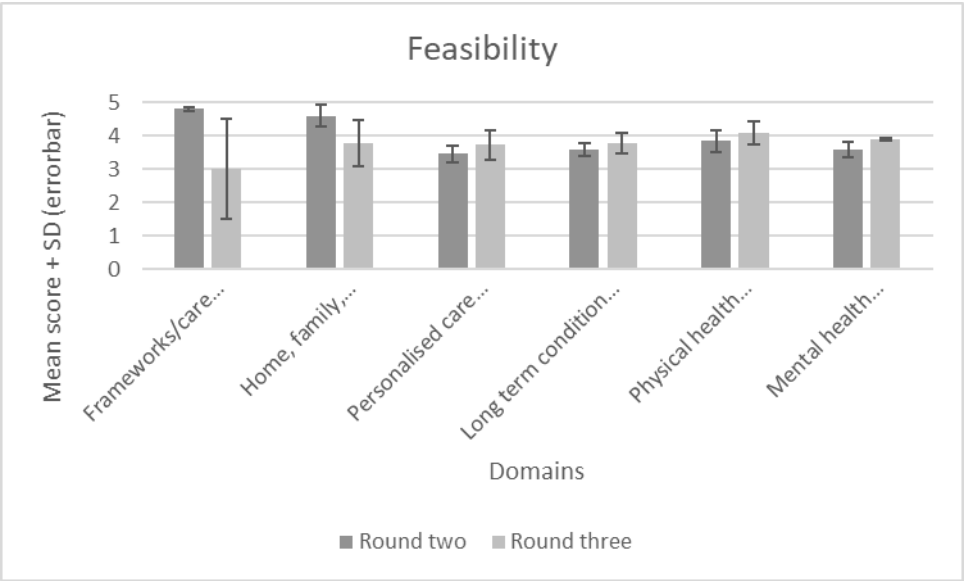


Figure 4.2b: Domain mean scores for feasibility (rounds two and three)



Generally, mean scores for importance remained high across all domains, with lower scores for feasibility. Scores relating to the domain of frameworks/care structures were higher in round three (mean 4.88; SD 0.13) than in round two (mean 4.80; SD 0.06) for importance, but with a larger standard deviation in round three, indicating more variability in scoring. However, feasibility scores reduced and had larger standard deviations from round two (mean 4.8; SD 0.06) to round three (mean 3.0; SD 1.5) indicating less consensus on feasibility of these components. The component relating to the need for a shared care record within this domain strongly influenced the overall mean score (mean 2.83; SD 0.75). Mean scores relating to the other four domains all increased from round two to round three with variable standard deviations; personalised care and support planning (importance: 4.55; SD 0.12 to 4.74; SD 0.12, feasibility: 3.47; SD 0.25 to 3.7; SD 0.44), long term condition management (importance: 4.53; SD 0.19 to 4.79; SD 0.18, feasibility: 3.59; SD 0.19 to 3.78; SD 0.31), physical health assessments (importance: 4.47; SD 0.36 to 4.72; SD 0.00, feasibility: 3.85; SD 0.32 to 4.10; SD 0.35) and mental health assessments (importance: 4.59; SD 0.11 to 4.82; SD 0.07, feasibility: 3.57; SD 0.23 to 3.9; SD 0.03). This may indicate overall convergence of opinion across rounds but with small numbers of outlying opinions which affected standard deviation.

4.6.4 Panel consensus

Following round three, all 36 components met consensus on importance, but only 11 out of the 36 components reached consensus on feasibility at the pre-defined level of 75% panel agreement (Table 4.2).

Table 4.2: Final percentages for each component (importance and feasibility)

Components	Importance	Feasibility
Frameworks/care structures		
Multi-disciplinary team discussion/review	100%	81.0%
Coordinated multidimensional assessment and care with an identified lead clinician	100%	76.2%
A competent, well trained workforce who can deliver the intervention	95.3%	47.6%
A timely response to crises	90.5%	19.1%
A system for data/information gathering e.g. past medical history, social circumstances	100%	47.6%
A shared care record	95.2%	57.8%
Home/family/safety assessments		
Environmental assessment aimed at maximising independence	95.2%	52.4%
Assessment of social support including financial concerns, social isolation	95.2%	47.6%
Assessment of functional ability and activities of daily living including reablement potential	95.2%	85.7%
Assessment of falls risk	100%	81.0%
Assessment of carer's needs	100%	66.7%
Determining spiritual needs and support systems	95.2%	57.1%
Exploring opportunities for employment/education/hobbies	81.0%	38.1%
Personalised Care and Support Planning		
Agreeing and formulating a plan together based on shared decision making	90.5%	57.1%
Safeguarding this contract by documenting it in a co-created care or support plan	85.7%	33.3%
Monitoring response to the care and support plan	85.7%	42.9%
Review and revising of the care and support plan	95.2%	61.9%
Empowerment and self-management and enabling behavioural change	95.2%	33.3%
Determining advance care preferences	100%	71.4%
Establishing the patient's personal goals and support needed (person centred care)	95.2%	81.0%
Assessment of resilience and coping mechanisms – an asset based approach	95.2%	33.3%
Escalation/contingency planning: actions for when the patient's condition deteriorates	100%	61.9%
Assessment of patient's ability to actively participate in care and planning	85.7%	76.2%
Establishing an individual's narrative by active listening/appreciative enquiry	90.5%	52.4%
Long Term Condition Management		
Medication review including ability to self-administer, concordance and de-prescribing	100%	81.0%
Advanced clinical assessment skills – physical examination and ordering investigations	90.5%	57.2%
Problem/deficit identification	95.2%	71.4%
Optimising management of long term conditions/multimorbidity	100%	71.4%
Physical Health Assessments		
Assessment for the presence and severity of frailty	90.5%	81.0%
Assessment of nutritional status including hydration	100%	85.7%
Sexual health assessment	81.0%	28.6%
Assessment of pain	100%	95.2%
Assessment of vision, hearing and dentition	100%	66.7%
Assessment of bladder and bowel function	100%	81.0%
Mental Health Assessments		
Assessment of cognition	100%	71.4%
Assessment of mood and psychological well-being	100%	66.7%

In the frameworks/care structures domain all components met the consensus threshold for importance (range 90.5 -100%), but four out of the six did not reach consensus on feasibility; a competent, well trained workforce (47.6%), a system for data/information gathering (47.6%), a shared care record (57.8%) and a timely response to crisis (19.0%).

In the home/family/safety assessments domain all components met the consensus threshold for importance (range 81.0 -100%), but five out of the seven did not reach consensus on feasibility; environmental assessment (52.4%), assessment of social support (47.6%), assessment of carer need (66.7%), determining spiritual needs (57.1%) and exploring opportunities for employment/education/hobbies (38.1%).

In the domain of personalised care and support planning all components met the consensus threshold for importance (range 85.7 -100%), but nine out of the eleven did not reach consensus on feasibility; formulating a personalised care and support plan (PCSP) (57.1%), documenting in a co-created PCSP (33.3%), monitoring response (42.9%), review of the PCSP (61.9%), empowerment and self-management (33.3%), determining advanced care preferences (71.4%), assessment of resilience and coping mechanisms (33.3%), escalation/contingency planning (61.9%) and establishing the narrative (52.4%).

All four components in the long-term condition management domain met the threshold for consensus on importance (range 90.5 -100%) while three of these did not achieve consensus on feasibility; advanced clinical assessment skills (51.2%) and problem/deficit identification and optimising long-term condition management (both 71.4%).

In the domain of physical health assessments, all components met the consensus threshold for importance (range 80.1% -100%), and two out of the six did not reach consensus on feasibility; assessment of vision, hearing and dentition (66.7%) and sexual health assessment (28.6%). Finally, in the domain of mental health assessments, both components of assessment of cognition and assessment of mood met the consensus threshold for importance (range 66.7 -100%), but not for feasibility scoring 71.4% and 66.7% respectively.

4.7 Discussion

The purpose of this e-Delphi study was to establish consensus on important and feasible components of a person-centred, nurse-led assessment and care model for frail older people in primary care. Following three rounds of surveys, the expert panel identified what they considered to be both important and feasible components of the care model and consensus at the required level for importance was reached for all suggested components. The important components are similar to those contained in the BGS CGA toolkit (Turner *et al.*, 2019), however, the panel did not think the majority of the components were feasible to deliver in current UK primary care. What is less clear is the reason for these beliefs. It may be that primary care nurses have concerns about the time and infrastructure available to complete a CGA or that there may be a lack of specialist skills.

There was clear concern demonstrated in the low feasibility scores for the existence of a shared care record to enable information gathering and sharing across organisations and the components that relate to personalised care and support planning. In 2013, the National Collaboration for Integrated Care and Support published its report “Integrated Care and Support: Our Shared Commitment” (National Collaboration for Integrated Care and Support, 2013) which stated the government’s pledge to end

institutional divisions and provide seamless health and social care for older people. The panel members' responses highlighted the importance of a competent, well trained workforce and demonstrated concerns about the feasibility of working across organisational boundaries in partnership to develop personalised plans of care. Studies have demonstrated the value of multi-professional involvement and a shared care record (Garrard *et al.*, 2020; Phelan *et al.*, 2007). It would seem that the reality in primary care is still far from the strategic vision of integrated care for older people.

Other components that were thought not feasible relate to the possession of specific skills by primary care nurses. It was interesting that the panel thought nurses would not be able to conduct an assessment of carer's needs, environmental assessments and determining preferred place of care. They also doubted the feasibility of nurses with advanced assessment skills. Some studies have reported a lack of specialist older people knowledge and skills amongst primary care nurses (Hertogh & Bastiaans, 2016; Hoogendijk, 2016) and it would appear that the expert panel in this study may share this view.

Notwithstanding the concerns already discussed, it was encouraging to see that specific components from other domains were thought to be important and feasible within a nurse-led approach. These were; establishing the diagnosis and severity of frailty and assessment of functional ability including re-ablement, falls risk, pain assessment, medication adherence and optimisation, nutritional status (including hydration) and bladder and bowel function. This is important information in the design of a nurse-led CGA-based approach as, to date, studies of primary care based CGA have demonstrated some benefits relating to clinical outcomes and acceptance by patients (Fenton *et al.*, 2006; Hermush *et al.*, 2009; Phelan *et al.*, 2007), however, they have not specifically detailed the content of the intervention under study. Transparency

about specific content would enable further evaluation or assessment in clinical practice.

The panel members had reservations about whether completion of CGA in current primary healthcare practice is possible and this reflects global concerns about shortage of primary healthcare professionals (World Health Organization, 2013) and the debate about how capacity and clinical quality can be increased by new models of care provided closer to home (Elkan *et al.*, 2001). They also echo results of other studies that highlight the perceived challenges to the delivery of primary care-based CGA (Craig *et al.*, 2015; Monteserin *et al.*, 2010; Stijnen *et al.*, 2014a). This may be an opportunity to examine who is the most appropriate clinician to provide care and support to frail older people with a view to increasing capacity within the primary care team and a more cost-effective and convenient approach for patients who would struggle to attend secondary care. Traditionally, in the UK, this is likely to involve a time-limited appointment with a GP (primary care doctor). A new model may include the substitution of nurses where care and treatment has previously been provided by doctors.

Ensuring the most appropriate clinician delivers care and support is an ongoing debate, with increasing acceptance that care for older people with complex needs can be led by nurses. Three systematic reviews have reported that care provided by nurses is of equal quality to care provided by primary care doctors (Horrocks, Anderson & Salisbury, 2002; Laurant *et al.*, 2005; Martínez-González *et al.*, 2014). Recently, the BGS affirmed that nurses are best placed to lead CGA-based approaches in primary care as they are “are well placed to manage the complexity of assessment in an efficient way drawing together the different strands to coordinate a personalised treatment plan” (Turner *et al.*, 2019, p.4). Turner *et al.* also emphasise that nurses have

a duty to act as patient advocate set out within their codes of conduct and are expert in enabling shared decision making. Given that CGA is a multi-dimensional assessment and care planning process, it has been advocated that multiple clinicians should be involved and that nurses are best placed to coordinate and lead the process ensuring best use of scarce resources and targeting of this approach at those who will most benefit (Schadewaldt *et al.*, 2013).

4.8 Study Limitations

Older people and their carers were not included in the expert panel and this was a limitation of the study in that the panel may not reflect views on what is important to them. In order to address this deficit, the Delphi findings were later shared with a research stakeholder group made up of older people, carers and clinicians to consult with them on the results of this study and final intervention content and delivery methods. Stakeholders agreed with the results of the e-Delphi survey but suggested some modification of components to improve personalisation and ensure the older person was able to express their views and concerns. Based on this, a conversation guide was added to the assessment pack (Supplementary Information 3 (Appendix 4)) which would be completed on first visit and guide the ongoing assessment and care planning process. This consisted of prompts to enable the older person to consider their own situation and engage in a conversation, which would lead to goal setting and care planning. It meant the approach would be uniquely person-centred and could address feasibility, as not all components of the assessment would be relevant to all people. This also has the potential to shorten and refine the assessment and care planning process and so add capacity to primary care services.

4.9 Conclusion

This e-Delphi study developed consensus on important and feasible components of a nurse-led, CGA-based approach in primary care. The study indicates which components of traditional CGA could be effectively delivered in primary care and which may not be as feasible in practice. It would seem that nurses may be the most appropriate clinician to lead this care in partnership with frail older people if there is a supportive infrastructure and sufficient numbers of skilled nurses available to meet the needs of the growing older population. There is now a need for development, further refinement and then feasibility testing of this new approach to ensure it is comprehensive and fit for purpose.

4.10 Implications for Practice

- The study indicates which components of traditional, hospital-based CGA may be effectively delivered in primary care and which components may not be feasible in practice.
- There is potential to develop a new care model that will be clinically effective, person-centred and can be delivered by nurses in primary care settings.
- This new approach has the potential to improve health outcomes, maximise independence and improve quality-of-life in frail older people.

4.11 Research Stakeholder Involvement

The remaining sections of this chapter are not part of the journal manuscript but provide more detail of the research stakeholder engagement that followed the e-Delphi survey.

The consensus components were drafted into an assessment pack to guide the assessment and care planning process. The final pack contained 33 assessment instruments which were evidence based tools relating to the components (Appendix 6). Given the low scores on feasibility there was concern that components that were important to frail older people and their carers could be omitted from the final intervention. A limitation of this study was that older people and their carers were not included in the expert panel. In order to address this, the results were shared with a research stakeholder group to consult with them on the final intervention, its content and delivery methods. Notes of the group meeting are included as Appendix 5.

The group consisted of two local clinical leads for older people's care, the researcher and one academic supervisor. The meeting was held at a local events centre. In addition, a local general practitioner, an older person and their carer were invited to attend, but could not, so, the researcher consulted with these stakeholders outside of the meeting. Information from the e-Delphi survey was sent to the general practitioner and a telephone meeting arranged at a convenient time to gain feedback. The researcher went to the home of the older person and their carer, sharing information with them and recorded their views on content of the final intervention. This additional stakeholder involvement was designed to ensure the intervention to be tested in the fRCT was fit for purpose. The stakeholders were asked to discuss the components from the e-Delphi survey and to prioritise and decide what should be included in the intervention with a focus on what could work in clinical practice and would meet frail older peoples' and carers' needs.

4.11.1 Results of the research stakeholder group

The group reviewed each component of the e-Delphi results and discussed and agreed whether it should be included or not within the HAPPI assessment pack and how it should be presented to ensure ease of use and feasibility in the trial.

Care Structures/Processes

These components included access to a shared system for information gathering (clinical record), multi-disciplinary team discussion/review, a timely response to crises and a competent, well-trained workforce to deliver the intervention. It was agreed that these components formed important feasibility outcomes for the trial, but were not elements of the assessment process. It was agreed that these elements would not be part of the assessment pack.

Nursing/Advanced Clinical Practice

It was agreed that tools to assess the presence or severity of frailty, falls risk, pain, medication review, nutrition/hydration/dentition, vision/hearing, bladder and bowel function, optimising long-term condition management and assessment of functional capacity should all be included in the assessment pack. Further discussion concluded that the conversation guide should also include prompts for problem/deficit identification, advance care planning and escalation/contingency planning. A personalised care plan template was under development in the county and it was agreed to use this template in the trial.

Mental Health

Stakeholders suggested that prompts to investigate mood and psychological wellbeing including anxiety and depression should be part of the conversation guide with more detailed assessments available in the assessment pack.

Social and Environmental Circumstances

Stakeholders suggested that this part of the assessment pack should be re-titled as “Home and Safety” and be included within prompts in the conversation guide such as “do you feel safe at home”, “is there anything regarding your home that concerns you?” An exploration of loneliness and social isolation was included within the mood and psychological well-being section. It was agreed that exploration of spiritual needs and support systems would be included in advance care planning discussions. Although assessment of carers needs did not reach consensus for feasibility in the e-Delphi survey, it was strongly felt by stakeholders that this was an essential element of the intervention and would be included in the conversation guide as a prompt.

Personalised Care and Support Planning

It was agreed to combine and include the components in this section as essential pillars of personalised care and support planning. Assessment of resilience and ability to participate in care planning were felt to be an important element of the intervention and so it was agreed to include them in the conversation guide prompts.

Intervention Delivery

The stakeholders fed back that the HAPPI intervention should encompass the following key principles that make the intervention unique and different to current care for this population:

- a) The person will not be referred in crisis (as in current community matron practice) but will be approached proactively following identification.
- b) The community matron who delivers the intervention will visit without first gaining any past medical history or other information about the person’s health from the general practice record and initiate an “unbiased, open dialogue” with

- the person. Any issues/problems/deficits will be generated from this dialogue and the assessment and care-planning intervention will develop from this point.
- c) There will be an ongoing development and review of a support plan in partnership with the person and carer (if appropriate).
 - d) Outcome measures will focus on responsiveness to change/completeness of the intervention and discharge plans; what is different after the intervention is complete.
 - e) The intervention will be based on a “conversation guide” rather than a prescriptive assessment template. Assessment tools will be available to be used if they are appropriate for that person’s needs/problems.

4.12 Chapter conclusions

In conclusion, the output from the Delphi survey combined with the research stakeholder consultation enabled the development of the HAPPI conversation guide, care plan templates and assessment pack, which formed the intervention for the fRCT (Appendix 6). The following chapter details the methods of the fRCT with embedded qualitative study.

Chapter 5: Evaluating feasibility of the Intervention

5.1 Chapter introduction

In this chapter, the methods of the fRCT are presented as a paper which was published in the Journal of Advanced Nursing 2019;00:1–10. DOI: 10.1111/jan.14106 (Lyndon *et al.*, 2019). The full trial protocol can be found in Appendix 7. An estimated contribution (%) of each author are as follows: Lyndon, H. (90%), Latour, J.M. (2%), Marsden, J. (2%), Campbell, S. (2%), Stevens, K. (2%), Kent, B. (2%).

HL generated the initial idea, wrote the study protocol and coordinated contributions from the other authors. HL, BK, JML, SC and KS made substantial contributions to conception and design. HL, BK, JML, SC and KS were involved in drafting the manuscript, revising it critically and gave final approval of the version to be published.

**The Holistic Assessment and care Planning in Partnership Intervention Study
[HAPPI]: A Protocol for a feasibility, cluster randomised controlled trial.**

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5.2 Abstract

Aim

During an initial phase of this research, an e-Delphi survey was conducted to gain consensus among stakeholders on the components of a nurse-led assessment and care planning intervention for older people who live with frailty in primary care. This feasibility randomised controlled trial (fRCT) will test the proposed intervention and its implementation and determine methods for the design of a conclusive randomised controlled trial.

Methods

The fRCT, with embedded qualitative study, aims to recruit 60 participants. Moderately and severely frail older people will be identified using the electronic frailty index (eFI) and the intervention will be delivered by senior community nurses. The control participants will receive usual primary care for frailty. The study is funded by the National Institute of Health Research (NIHR) (funding granted in May 2016, ref: ICA-CDRF-2016-02-018) and received NHS and University Ethical approval in 2018.

Discussion

There is evidence that the delivery of complex interventions for community-dwelling older people can reduce care home and hospital admissions and falls, there is less evidence for the benefit of any specific type or intensity of intervention or the additional benefits of targeting the frail population. This trial will determine feasibility of the intervention, define recruitment and retention parameters and trial logistics and decide outcome measures.

Impact

This study aims to address the limitations of current research by using a systematic method of frailty diagnosis and participant identification, trialling implementation of a person-centred intervention and testing of feasibility parameters.

Trial registration number: ISRCTN: 74345449

Key Words

Older people; frailty; primary care; nursing; assessment; holistic intervention.

5.3 Introduction

Frailty is a multifactorial clinical syndrome associated with ageing. It is caused by incremental damage to body cells and systems as individuals' age (Cesari, Vellas & Gambassi, 2013; Rockwood & Mitnitski, 2007). Although its specific pathophysiology is not fully understood, it is known to follow similar mechanisms to sarcopenia (muscle weakness), malnutrition and is underpinned by de-regulation of inflammatory processes (Cesari *et al.*, 2014b; Jeejeebhoy, 2012; Li, Manwani & Leng, 2011). Although associated with older age, frailty can be distinguished from the effects of natural ageing. Frailty manifests when multiple body systems fail, the more systems that fail, the more likely it is that the person will become frail (Clegg *et al.*, 2013; Morley *et al.*, 2013). As people age, there is a loss of physiological reserve in all body systems, however, there is an intrinsic reserve buffer which enables homeostasis to be maintained and good function preserved. Once this threshold is breached then frailty will result with repair mechanisms no longer able to maintain homeostasis (Lang, Michel & Zekry, 2009). Other independent risk factors for frailty development include loneliness (Gale, Westbury & Cooper, 2018), deprivation (Hoogendijk *et al.*, 2014), depression (Vaughan, Corbin & Goveas, 2015), low physical activity and polypharmacy (Heuberger, 2011).

Given the multifactorial nature of frailty, an effective intervention should address relevant risk factors using a holistic, multi-dimensional approach. This approach is the founding principle of a comprehensive geriatric assessment (CGA) which is described as the management and treatment for prevention of deterioration in frailty (Gladman, 2016). The British Geriatrics Society describe CGA as

“a multidimensional, interdisciplinary diagnostic process to determine the medical, psychological and functional capabilities of a frail older person in order to develop a

coordinated and integrated individualised care plan for treatment and long-term follow up in partnership with the patient and carers”

(British Geriatrics Society, 2014, p.10).

This approach is part of routine care and well evidenced in the acute hospital setting within the speciality of geriatric medicine, but not well established in other healthcare settings such as primary care. To meet the challenges of the increasingly frail and older population and to provide proactive, holistic care close to home, there is a need for a standardised intervention that can be implemented in primary care, which provides value for money, is not time consuming and has a high level of specificity to enable primary care resource to be targeted at patients who will most benefit from the intervention. If a primary care led standardised intervention is to become a reality, the burden of completion and effect on patient outcomes require further research as to the feasibility, acceptability, effectiveness and scalability. Informed by the existing literature and patient and public engagement (PPI), a primary care intervention that contains cost and clinically effective components of the acute CGA framework was developed.

An e-Delphi survey was conducted to gain consensus among stakeholders on the components of the intervention. After mapping the components, a new intervention was developed including a conversation guide and assessment pack to structure the intervention to be tested in a feasibility randomised controlled trial (fRCT). This paper presents the study protocol of the fRCT.

5.4 Background

There is increasing evidence that, using a person-centred approach, frailty can be managed as a long-term condition with early identification, diagnosis and effective management in order to improve outcomes, prevent or delay deterioration and reduce

health and social care costs (De Lepeleire *et al.*, 2009; Lee, Heckman & Molnar, 2015). Although they advocate the management of frailty in primary care settings De Lepeleire *et al* acknowledge that the identification of frailty and its application to clinical practice in this area are under-developed. Given its high prevalence, frailty management is likely to become the remit of primary care in the future. However, there may be insufficient capacity and lack of appropriate skills and knowledge in primary care settings to adequately manage numbers of frail patients. If an achievable, proactive model of care is developed, primary care is the ideal setting to implement a more person-centred approach because of the integrated nature of primary and community care and the opportunities to interact with patients in their home environment (Beswick *et al.*, 2008).

In 2014 the British Geriatrics Society (BGS) suggested that a primary care led 'holistic review' by a GP or specialist nurse may enable more frail older people to access services out of hospital. However, as previously discussed, it is not clear whether the acute hospital CGA framework is immediately transferable. The BGS have suggested other considerations that are missing from the traditional CGA framework, such as treatment escalation and advanced care planning (British Geriatrics Society, 2014). These considerations would appear to be highly relevant as part of a CGA intervention delivered in a primary care setting where the clinician has a more long-term and person-centred relationship with the patient. A recent review of person-centred care concluded that while there is no universal definition of the concept, there are well recognised behaviours displayed by nurses that promote person-centeredness, such as engaging with the patient as a partner and shared decision making (Sharma, Bamford & Dodman, 2016). These behaviours and their foundation in nurses'

approaches to care would appear to make nurses appropriate clinicians to carry out CGA/holistic review in a primary care setting.

5.5 Aim and Objectives

The aim of this fRCT with an embedded qualitative study is to determine the feasibility of delivering the Holistic Assessment and care Planning Intervention (HAPPI) in primary care to older people with frailty and determine methods for the design of a conclusive randomised controlled trial (RCT). Detailed objectives of the trial are described in Table 5.1.

Table 5.1: Trial objectives

Objectives a-h will be met within the feasibility randomised controlled trial:

- a. To assess compliance with the HAPPI intervention.
- b. To verify that proposed outcome measurement and follow-up schedules are feasible to collect.
- c. To determine achievable targets for recruitment and follow-up rates.
- d. To evaluate method of recruitment using the electronic frailty index (eFI).
- e. To evaluate characteristics and feasibility of the proposed outcome measures and to determine suitable outcome measures for the definitive trial. Outcome measures to be evaluated have been taken from the ICHOM Older Persons Reference Guide (Akpan *et al.*, 2018).
- f. To calculate standard deviation of the outcome measures to estimate sample size for the definitive trial.
- g. To assess availability of clinical data and time needed to collect and analyse data required for numeric outcome measures.
- h. To explore factors that will enable future economic evaluation alongside the main trial.

Objectives i-l will be met within the embedded qualitative study:

- i. To explore the acceptability of the intervention to patients, carers and clinicians in primary care.
- j. To identify barriers to delivery of the HAPPI intervention e.g. any operational difficulties.
- k. To evaluate clinicians' willingness to identify, recruit and randomise eligible patients, and willingness of patients to be recruited and randomised.
- l. To explore the acceptability of trial processes and collection of outcome measures to participants.

5.6 Methodology

The trial will be a cluster randomised, controlled feasibility trial with an embedded qualitative study aiming to recruit 60 participants from six general practices. Cluster randomisation with the general practice as the unit of randomisation has been proposed to reduce contamination between control and intervention groups which may lead to biased estimates of effect size in the main trial. Three general practices will be allocated to the intervention and three to the control arm of the study, so that patients of individual general practices will either receive the intervention or usual primary care. As the HAPPI is an intervention that aims to impact on staff expertise, awareness and clinical practice, it is important to ensure separation of the control and intervention groups in this way. Fig 5.1 shows the flow diagram of the study design.

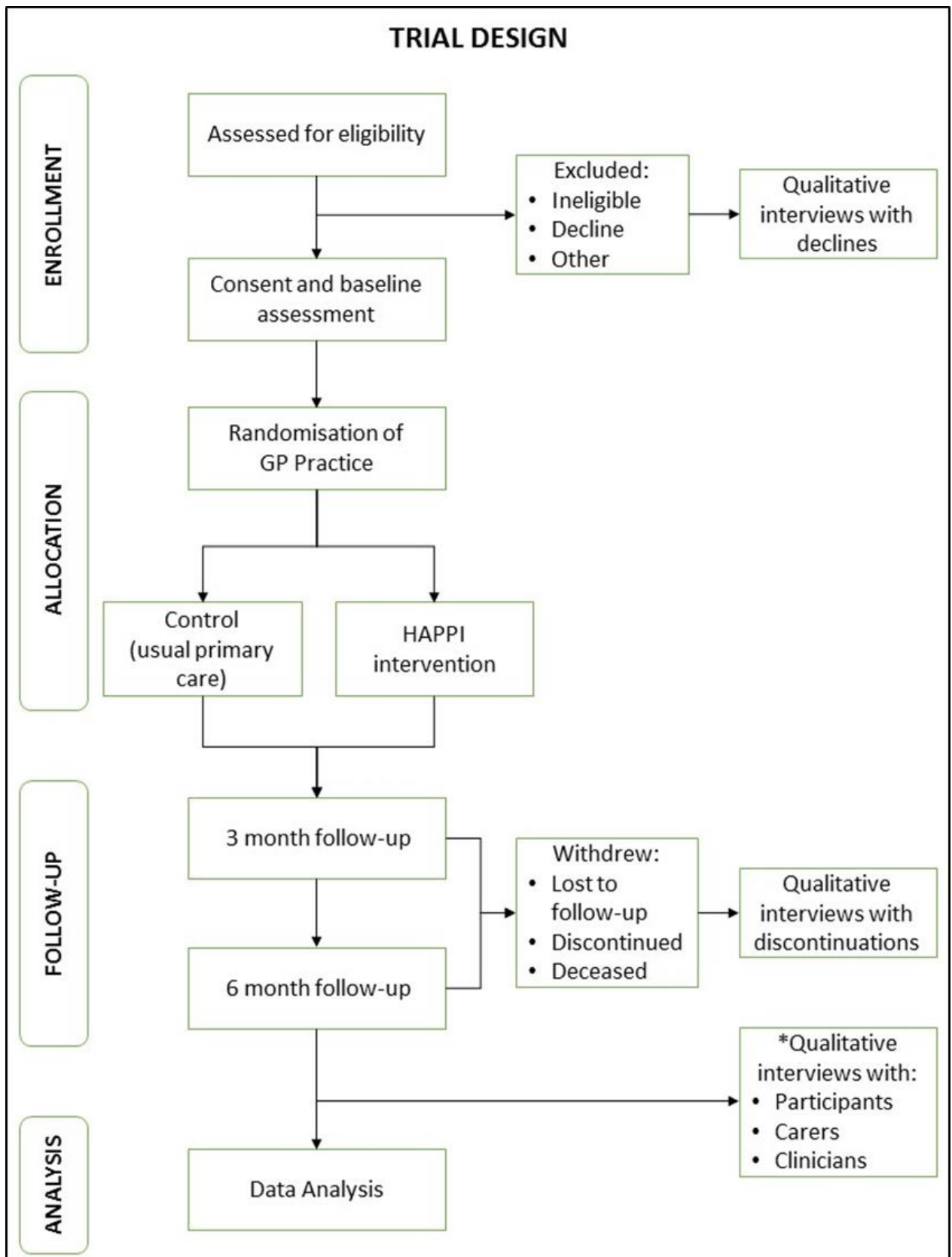


Figure 5.1: Flow chart of the study design

5.6.1 Study Setting and General Practice Eligibility

Six general practices will be recruited to the study. The following factors will be used to determine suitability of practices to participate in this study:

- a. The practice use the electronic frailty index (eFI) to identify their moderately and severely frail population
- b. The practice are willing to fulfil the requirements of the study relating to screening, recruitment and provision of outcome data
- c. There is at least one senior community nurse attached to the practice who is willing to deliver the HAPPI intervention

General practices registering an interest in the trial will be invited to complete a feasibility questionnaire to assess their suitability which will be checked by the Chief Investigator. Reasons for non-selection of practices will be fully documented to inform feasibility objectives.

5.6.2 Recruitment

Under the terms of the NHS England General Practice Contract (NHS England, 2017), practices are required to identify moderately or severely frail patients aged 65 years and over in their practice population. Practices use an appropriate evidenced based tool such as the electronic frailty index (eFI) (Clegg *et al.*, 2016). The eFI is a computerised algorithm that is integrated into the majority of general practice electronic clinical records and is used to identify and grade severity of frailty using a cumulative deficit model based on a number of variables that including clinical indicators, long-term conditions, disabilities and abnormal test results (Clegg *et al.*, 2016).

In order to generate a list of the moderately and severely frail patients, a practice administrator will run the eFI as a database search and this will classify the entire

practice population into fit, mildly frail, moderately frail and severely frail people. The output from the eFI, combined with the application of the trial inclusion/exclusion criteria, will identify initial potential participants for the trial.

Potential participants will be eligible for the study provided they are:

- a. Aged 65 years and over
- b. Moderately frail: Electronic Frailty Index (eFI) >0.24 to 0.36 or severely frail (eFI > 0.36)
- c. Frailty confirmed by PRISMA7 instrument
- d. Able to give informed consent
- e. Living in own home/supported living accommodation

Patients in receipt of palliative care with limited life expectancy, those who lack mental capacity to give informed consent or if they are already on the caseload of a senior community nurse will be excluded from the study.

Ninety potential participants will be randomly sampled from the eFI list, 45 in the moderate and 45 in the severely frail categories. If there are less than 45 in either category then sampling will not occur and all patients go forward for eligibility checking. The eFI is a population risk stratification tool and cannot confer clinical diagnosis, therefore, a further step is required to make a diagnosis of frailty and confirm eligibility. Frailty diagnosis will be confirmed by the completion of the PRISMA7 questionnaire (Raiche, Hebert & Dubois, 2008). An invitation to participate in the trial and PRISMA7 will be sent to the 90 people. Names of interested patients who meet PRISMA7 criteria will be passed to the research team who will make contact. An appointment will be made for a visit at home or in the general practice to provide choice and minimise participant burden. During this consultation, the participant will be given the opportunity

to ask further questions about the study before consent is obtained and baseline assessments carried out.

5.6.3 The intervention

Participants in the intervention group (n=30) will receive the HAPPI intervention delivered by a senior community nurse who has received training in its delivery. Senior community nurses are experienced nurses with advanced assessment and prescribing skills, the required skills set to deliver the assessment and care planning intervention. They are attached to individual general practices and employed by the community services NHS Trust. In order to ensure a standardised approach, training will be given prior to delivering the intervention using a training package delivered by face-to-face training by the Chief Investigator.

A conversation guide, assessment pack and personalised support plan template have been developed to support delivery of the intervention and ensure treatment fidelity by detailing the content of the intervention and how it should be delivered. The intervention will be delivered at home and it is expected that it will consist of one assessment visit and up to six care planning visits conducted over a maximum of 12 weeks. For the purpose of the trial, the minimum “dose” of the intervention will be defined as one assessment visit and at least two care planning visits. Documentation of the intervention, including assessment, support plan and evidence of any referrals, will be recorded using a standardised template, which will be stored in the clinical record.

5.6.4 Control

Participants in the control group (n=30) will receive usual care. This cannot be standardised as approaches to care of older people with frailty varies in general practice (British Geriatrics Society, 2014). This may include the management of long-term conditions, referrals to other services, prescribing of medications and routine

vaccinations. As part of the feasibility trial, components of usual care will be captured in order to standardise for the future definitive RCT.

5.6.5 Outcomes

The primary outcomes relate to feasibility of the intervention, feasibility of conducting the trial and assessing different potential primary and secondary outcomes of the future trial and are summarized in Table 5.1. All potential clinician and participant-reported primary and secondary outcome measures will be collected at baseline (following randomisation and consent), three months (post intervention) and six months post intervention.

Table 5.1: Trial outcome measures

Feasibility of the Intervention
<ul style="list-style-type: none"> a. Numbers of completed HAPPI intervention conversation guides and personalised care plan templates b. Assess degree of contamination by number of staff moving between intervention and control practices
Feasibility of Conducting the Trial
<ul style="list-style-type: none"> c. Number of GP practices expressing an interest in participating d. Number of GP practices screened for selection and reasons for non-selection e. Number of GP practices withdrawing from the study, timing and reason for withdrawal f. Number of GP practices failing to progress through implementation milestones and reasons for failure g. Number of GP practices withdrawing during the implementation and delivery phases h. Numbers of participants screened as eligible, recruited, consented and followed up i. Numbers of participants identified using the electronic frailty index (eFI) j. Number of and timing of participant withdrawals from follow-up data collection, reasons for withdrawal, number of and timing of losses to follow-up
Potential Primary and Secondary Outcomes
<ul style="list-style-type: none"> k. Numbers of potential primary and secondary outcome measures completed at baseline and follow-up intervals l. Numbers of missing items for each potential primary and secondary outcome at each time-point m. Estimation of the feasibility of collecting data to estimate cost-effectiveness; EQ-5D-5L; add-on for economic evaluation (Janssen <i>et al.</i>, 2013). n. Assessment of the following outcome measure instruments: <ul style="list-style-type: none"> • Review of usual care practice, using a clinical note review of control participants • Level of care at home received measured by participant self-reporting • Polypharmacy – number of medications prescribed and participant perception of adverse effects

- Levels of loneliness and isolation measured by UCLA 3-Item Loneliness Scale (Velarde-Mayol, Fragua-Gil & García-de-Cecilia, 2016)
- Physical health and mobility, level of pain, mood and emotional health and health-related quality of life measured by the Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36) (Ware & Sherbourne, 1992)
- Confidence in own ability to manage health and in role as participants in care measured by the Health Foundation LTC6 questionnaire (Akpan *et al.*, 2018)
- Mortality; date and cause of death obtained from the clinical record
- Number of hospital admissions, readmissions and total number of days spent in hospital obtained from the clinical record

The Medical Research Council guidance (Craig *et al.*, 2008) highlights the need to explain causative mechanisms and describe contextual factors associated with variation in outcomes. Process evaluation will form part of feasibility assessment. This highlights the importance of capturing fidelity, which includes assessing whether the intervention was delivered in the correct dose/quantity and to the expected number of participants.

Fidelity will be measured in a variety of ways; nurses delivering the intervention will receive standardised training and use a conversation guide, assessment pack and personalised support plan template as a framework for the intervention. They will record the completed components of the intervention and any adverse events related to the intervention.

5.6.6 Data collection and storage

Data will be collected through the completion of case report forms consisting of three sections relating to intervention delivery, participant outcome measures and data from the clinical record. In addition a screening log will be completed by the general practice,

detailing numbers of participants screened, those eligible, responses to recruitment letters and those who progress to consent or decline to participate.

A customised database will be used for data entry and double entered data compared for discrepancies. Anonymised data will be securely stored for ten years after the completion of the trial in accordance with University policy. The Sponsor will be responsible for archiving all trial data following submission of the end of study report. In data gained from interviews all participants will be anonymised and pseudonyms used to demonstrate different participants' experiences.

5.6.7 Data analysis

As a feasibility study, a formal sample size calculation based on considerations of power is not appropriate (Thabane *et al.*, 2010). This study is not powered to detect clinically meaningful between-group differences in a primary outcome. One of the aims of the study is to provide accurate approximations of recruitment and follow-up rates, as well as provide estimates of the variability of the proposed primary and secondary outcomes to inform sample size calculations for the planned definitive trial. There is no consensus on the recommended number of participants required for a feasibility study, with suggested numbers ranging from 20 to 70 or more participants when the planned primary outcome is of a continuous nature. (Whitehead *et al.*, 2016). Therefore, this feasibility study aims to recruit 60 participants in total.

Participants will be recruited from a minimum of six general practices, with a total practice population of 491,000. The planned recruitment period is six months and over this period, across the practices, it is anticipated that following initial screening (eFI), approximately 9000 (1500 per practice) potential participants will be identified and from these 540 (90 per practice) sampled for second screening (PRISMA7) and eligibility.

Following second screening, it is estimated that around 30% of eligible participants will consent to participate. The follow-up rate is estimated to be 70%, which would provide follow-up outcome data on a minimum of 42 participants across both allocated groups and three sites.

As a feasibility study it would be inappropriate to test treatment effects, therefore the statistical analyses will be descriptive in design (Thabane *et al.*, 2010). The statistical analysis plan will conform to guidance related to statistical analysis plans (Gamble *et al.*, 2017) and take into consideration the CONSORT updated guidelines for reporting feasibility and pilot trials (Eldridge *et al.*, 2016) and also give consideration to the CONSORT Patient-Reported Outcome (PRO) extension: Health and Quality of Life Outcomes (Calvert *et al.*, 2013) and CONSORT Statement for Randomised Trials of Non-pharmacologic Treatments (Boutron *et al.*, 2017). All analyses and data summaries will be conducted on the intention-to-treat (ITT) population which is defined as all participants randomised regardless of non-compliance with the protocol or withdrawal from the study. Participants will be analysed according to the intervention they received.

The aim of the analysis is to assess the feasibility of the intervention, the feasibility of a full definitive trial and summarise potential primary and secondary outcome measures. A summary of the planned statistical analysis methods are presented in Table 5.2.

Table 5.2: Statistical Analysis Methods

<p>Measuring feasibility of the trial will include:</p> <ul style="list-style-type: none"> • CONSORT diagram • timing of follow-up assessments (i.e. where they within a reasonable time frame) • time taken to recruit sites/participants • balance of baseline characteristics by allocation group • number of research assessors who became unblinded • movement between practices (although potentially this may not be representative of the country)
<p>Feasibility of the intervention will include:</p> <ul style="list-style-type: none"> • numbers who complied • how much participants complied with intervention (i.e. one assessment and at least two care planning visits)
<p>Potential primary/secondary outcomes assessment will include:</p> <ul style="list-style-type: none"> • summary statistics difference between baseline and follow-up visits • completeness of data (missing completely and missing items)

5.6.8 Embedded Qualitative Study

This component of the trial explores the experiences of the study participants, their carers, clinicians who will deliver the intervention and general practice staff who facilitate recruitment and eligibility screening. The aim is to generate recommendations and address unknowns including experiences of recruitment, retention, practical implementation and further refinement of the intervention and outcome measures for the design of the future RCT.

5.6.8.1 Methodology

The research team will conduct in-depth semi-structured interviews to gain insight into their experiences in participating in the study from participants, carers, community nurses and practice administrators.

5.6.8.2 Sampling

A sample of participants will be invited for interview based on severity of frailty (equal numbers across moderate and severe). Half the sample of participants and carers will be interviewed at three months post-randomisation and half at six months to gain insight at each stage of the trial. Senior community nurses who delivered the intervention will be approached for interview and practice administrators who conducted screening and recruitment procedures. Maximum sample numbers are described below but if saturation is reached prior to these numbers, no further interviews will be conducted. The following purposive sample size is anticipated:

- A maximum of six study participants (four from the intervention arm, two from the control arm of the RCT).
- Four carers of study participants (two intervention arm, two control arm of the RCT).
- Two people who declined to participate at the outset, and two people who withdrew from the study before completion.
- A maximum of six senior community nurses who delivered the intervention.
- Four general practice administrators who implemented recruitment and eligibility screening procedures

It is understood that it might be ethically challenging to recruit to the qualitative study once a participant has declined the feasibility RCT. However, the importance of

including these people is to explore their reasons for declining participation or withdrawal in order to use these data to inform the larger study protocol and maximise recruitment and retention.

5.6.8.3 Qualitative data collection

In-depth semi-structured interviews will be undertaken using an interview protocol and topic guide which comprises of open questions relating to structure, process and outcome of the trial. For clinicians, topics will include situations they found interesting with regard to implementation of the HAPPI intervention and any challenges with regard to its delivery. Interviews with practice administrators will explore their experiences of the identification, screening and recruitment procedures. For patients and carers topics will include their experiences of the HAPPI intervention, participating in the trial and completing outcome measures questionnaires. All interviews will be audio recorded and transcribed verbatim. Interviews with patients and carers will be conducted at the patient's own home following an informal format, to assist in helping participants to share their experiences and allay any concerns that they are being too critical. Interviews with community nurses and practice administrators will be conducted at their local work base. It will be re-iterated that all data will be anonymised and that interviewers are interested in all participants' views and opinions and will not make judgements.

5.6.8.4 Decliner and withdrawal interviews

Up to two people who declined to participate at the outset will be interviewed and another two people will be interviewed if there are participants who withdraw once consented into the trial. At the time they decline to participate in the study, or withdraw, they will be asked once only if they would be willing to share their reasons why they declined in a brief interview. They will be informed that the researchers

would find any reasons they had for declining useful for developing this and future research. They will be clearly informed that this is entirely optional and they do not have to share their reasons. If they consent, they will be given an option to be interviewed alone or with their significant other. The aim is to explore their feelings about this feasibility study and reasons for declining or withdrawing in order to inform and optimise recruitment/retention for the remainder of the trial and subsequent main study. Data collection will occur within three days of declining or withdrawal.

5.6.8.5 Qualitative data analysis

Qualitative study results will be reported using the COREQ checklist for interviews and focus groups (Tong, Sainsbury & Craig, 2007). Thematic analysis will be used to analyse the data. This method includes a strategy for identifying themes and subthemes (Braun & Clarke, 2006). The interview transcripts will be uploaded to the qualitative analysis program NVivo. The first analysis step will involve two researchers becoming familiar with the narratives by reading the transcripts independently. In the next step, two researchers will independently code the text by allocating the text fragments to codes. The codes will be formulated from the text fragments and will possibly be revised during the process of reading the transcripts. Two researchers will then discuss the results of the individual codes and try to reach consensus. After this, the codes will be reviewed and themes will be formulated.

5.6.8.6 Qualitative data presentation

Demographic data items will be presented using descriptive statistics. Meaningful text fragments will be determined, as will codes (sub-themes) and themes related to the trial objectives. Data extracts will be accompanied by extracts from the transcripts to elaborate why the extract is interesting as part of analysis.

5.6.9 Ethical Considerations

This study protocol was approved on 16th October 2018 by the National Health Service Research Ethics Committee (REC reference: 18/LO/1354; IRAS project ID: 229210) and the University Research Ethics Committee on 14th November 2018 (Reference Number: 18/19-1027).

Protection of participants and researchers from harm is paramount. The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Policy Framework for Health and Social Care Research.

5.6.10 Consent, confidentiality and data protection

All eligible people who have agreed to be approached by completion of the recruitment invitation letter will be given verbal and written information about the study. Information will be provided in an appropriate form, for example a supported conversation around written material (a patient information sheet) to maximise understanding of what is being asked of them and to support them to make decisions. The patient information sheet is available in large print if required. People will be informed that their care will not be affected in any way by their decision to take part or not.

People willing to take part in the trial will be invited to provide confirmation of informed consent to undergo baseline and follow-up assessments and data collection, and permission to access to patient's medical and social care records will be sought. If the person has capacity to consent but cannot sign the consent form, this will be indicated on the consent form by the assessor.

Data will be collected and stored in accordance with the Data Protection Act 1998/General Data Protection Regulation 2018 (*Data Protection Act*, 2018). All paper

documents will be stored immediately after use securely in the Site File at each site separate from study data. All computerised data will be stored on a password protected device. After completion of the trial these will be accessible for the purposes of monitoring and auditing via the Sponsor who will be storing the anonymised data for ten years. All identifiable data will be destroyed as soon as the trial has ended and participants have been sent a summary of the results.

5.7 Discussion

Research into the management of frailty as a long-term condition and specifically in primary care is high priority for policy makers nationally and internationally. This study aims to test the feasibility of a uniquely person-centred approach to assessment and care planning led by nurses in partnership with patients and their carers. Testing feasibility is one of the key principles of developing a complex intervention (Moore *et al.*, 2015) in order to assess acceptability and develop important parameters for a definitive trial. Research suggests that this preparatory work is often not undertaken fully leading to errors in design of full trials (Eldridge *et al.*, 2004) and that interventions that would have made a difference fail due to challenges of delivery, implementation and compliance (Bower, Wilson & Mathers, 2007; Prescott *et al.*, 1999).

There is some evidence that the delivery of complex interventions for older people at home can reduce care home and hospital admissions and falls, however, less is known about the benefit of any specific type or intensity of intervention (Beswick *et al.*, 2008). In addition, Beswick's systematic review notes that there was a lack of identification and recruitment of frail older people to studies and, therefore, we do not yet understand the additional benefits of targeting the frail population.

The nursing contribution to the management of frailty is poorly developed with few well-designed studies assessing nurse-led interventions showing mixed results, again with very few focussing on targeting the frail population. Few studies have specified the content of the intervention and the competencies required by clinicians delivering the intervention (Gardner *et al.*, 2017; Jovicic *et al.*, 2015). One study has shown that nurses may be the most appropriate clinician to deliver a primary care-led intervention, but highlighted the issue of lack of treatment fidelity and identification of the most frail (Godwin *et al.*, 2016).

5.8 Conclusion

This study aims to increase the evidence and to address the limitations of current research. This will be achieved by the use of a systematic method of frailty diagnosis and participant identification, implementation and testing of the acceptability of a uniquely person-centred intervention which is not prescribed or regimented but developed iteratively based on the needs and aspirations of the frail older person. It will enable testing of feasibility parameters to maximise success of a future definitive trial by exploring the views of all major stakeholders including participants, carers and clinicians.

Chapter 6: Feasibility Randomised Controlled Trial Results

6.1 Chapter Introduction

This chapter presents the results from the feasibility RCT. As this is a feasibility trial, descriptive statistics are presented relating to the feasibility objectives concerning eligibility (sites and participant), consent, recruitment, randomisation, experience and content of the intervention, safety, summary of missing data and baseline and demographics of the participants. The aim was to test trial procedures and determine acceptability to participants and clinicians. Progression to a full trial is considered viable if pre-specified criteria are met or if clear strategies are identified that could support the delivery of the full trial following successful identification of a suitable primary outcome.

6.2 Eligibility

6.2.1 Site Eligibility and retention

The trial aimed to recruit six sites (general practices) located in Cornwall, UK. General practices registering an interest in the trial were invited to complete an eligibility questionnaire (Appendix 8) and those who fulfilled the required criteria were invited to take part in the study as sites. Out of the 14 general practices approached, eight met eligibility criteria and six progressed as sites; these were the first six who confirmed participation (Table 6.1). Reasons for non-selection of practices included lack of a community matron in post or absence of the eFI within the electronic clinical notes system.

Table 6.1: Site eligibility and retention

Variable	n (%)
Number of general practice sites approached to participate in the study	14
Number (%) of general practice sites who were initially approached progressed to participating in the study	6 (42.8)
Number (%) (ratio) of general practice sites approached who met initial eligibility criteria	8 (57.1)
Number (%) of general practice sites who withdrew from the study prior to completion	0 (0.0)
Number (%) of sites completing screening/eligibility processes as per study protocol	6 (100.0)
Number (%) of sites completing screening/eligibility processes within prescribed timescale (6 months from site initiation)	5 (83.3)

No sites withdrew from the study prior to completion, however, one site needed significant support from the research team including help to generate the eFI list and apply eligibility criteria. This site would have withdrawn without that support. All sites eventually completed all screening and eligibility processes in line with the protocol, however, there were some protocol deviations which are discussed in section 6.7. Five sites completed screening procedures within the prescribed timescale. The one practice that did not complete within the timescale had to repeat some procedures due to protocol deviations and difficulty in contacting the lead person at the site for a prolonged period of time led to delays.

6.2.2 Sampling

A total of 3292 moderately frail and 796 severely frail people were identified using the eFI across the six sites. To reduce the numbers of this initial cohort, a random sampling approach was used to create the initial enrolment sample. The clinical trials unit provided a list of 90 random numbers that was applied to the eFI list at each site. This

meant that no patient identifiable information left the site until consent was obtained. A total sample of 414 potential participants were identified at this stage of screening. While it was planned to identify 90 at each site (540 in total), three sites identified less severely frail people than anticipated.

6.2.3 Participant enrolment, screening and eligibility

Out of the 414 sampled, n=87 people (21.0%) were not eligible. Number and reasons for ineligibility are presented in Table 6.2, and the CONSORT flow chart (Figure 6.1). All data related to participant screening, enrolment, randomisation and follow up of individual participants are reported in the CONSORT flow chart (Eldridge *et al.*, 2016) (Figure 6.1). As a cluster randomised controlled trial, there are specific features which require additional reporting in accordance with the CONSORT statement for the reporting of cluster randomised trials (Campbell, Elbourne & Altman, 2004) including the flow of both clusters through the trial, from assignment to analysis. In this study, there were six clusters (three assigned to intervention and three to control). No clusters withdrew or were lost to follow-up and data was analysed from all six. The mean cluster size in the intervention allocation was 10 participants, 8.67 participants in the control arm. The cluster cohort flow chart is included as Appendix 9.

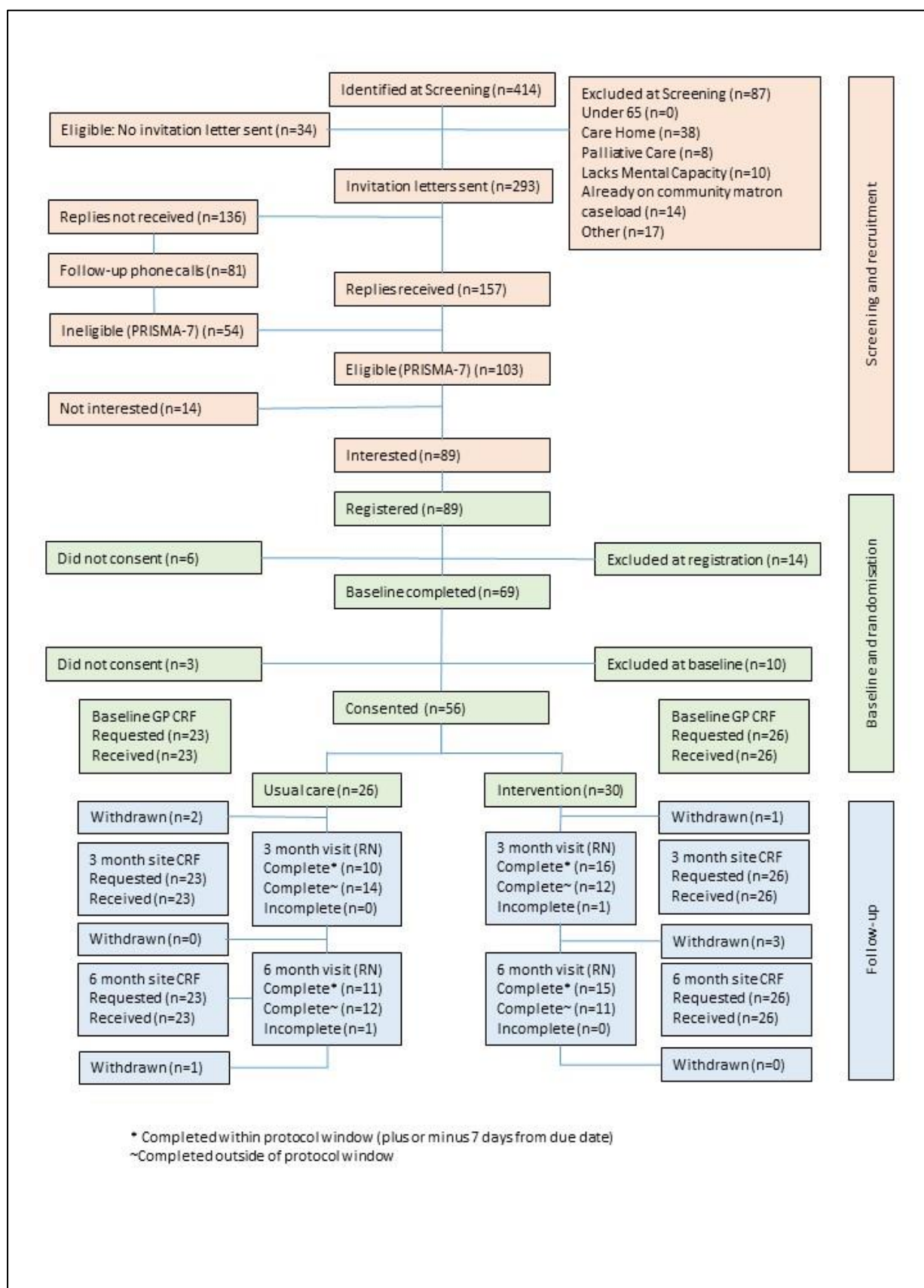


Figure 6.1 CONSORT Flow Chart

Table 6.2: Reasons for ineligibility

Reason not eligible	Number of participants % (n)
Resident in care home	43.7 (38)
In receipt of palliative care	9.2 (8)
Lacks mental capacity to consent	11.5 (10)
Already on community matron caseload	16.1 (14)
Other	19.5 (17)

Following eligibility screening, invitation letters (Appendix 10) were sent to 293 people. There were 136 (46.4%) people who did not respond to the letter and 81 phone calls were made by administrators to pursue a response. In total, 157 (53.6%) replies were received to the invitation letter expressing interest in participating in the trial. Of these, 54 (34.4%) respondents were found to be ineligible on PRISMA7 questionnaire. The remaining (n=103) were contacted by phone by the research team to give more information about the trial and discuss participation further. After this contact, 89 (86.4%) remained interested in participating and were registered onto the trial database. Exclusions at registration totalled n=14 (15.7%) and reasons for exclusion included, not meeting eligibility criteria or that the numbers required for the trial were already met. For the latter, the Chief Investigator (CI) contacted them and thanked them for their interest in participating and explained why they would not be included at this point. Baseline and consent visits were completed with 69 people, and of these, three did not consent and ten were excluded at baseline visit on final eligibility check. A participant information sheet (PIS) (Appendix 11) was provided and after the opportunity to ask questions, if the person was still willing to participate then consent was recorded on the informed consent form (Appendix 12).

6.3 Recruitment

A total of 56 participants were recruited to the trial and randomised within the anticipated timeframe (Figure 6.1). Numbers of participants screened and randomised plus withdrawals by site are summarised in Table 6.3.

Table 6.3 Number of participants screened and randomised by site

	Intervention sites			Control sites		
Variable	Site 01	Site 02	Site 05	Site 03	Site 04	Site 06
Numbers n (%) screened						
Total	61 (14.7)	90 (21.7)	90 (21.7)	50 (12.1)	33 (7.8)	90 (21.7)
Reasons for non-participation (n)						
Did not meet inclusion criteria	10	26	6	11	3	32
Invited to participate	51	64	60	30	30	58
Ineligible on PRISMA-7	5	10	14	12	0	13
Declined to participate or did not respond to invitation	34	40	26	7	18	26
Did not consent	1	2	0	1	1	1
Registered to trial database	11	12	20	11	12	19
Number n (%) randomised*						
Total	10 (17.8)	10 (17.8)	10 (17.8)	9 (16.1)	7 (12.5)	10 (17.8)
Number n (%) discontinuation/withdrawal						
Total	1 (1.7)	1 (1.7)	2 (3.6)	2 (3.6)	0 (0.0)	1 (1.8)
Number n (%) of participants data fully analysed						
Total	9 (90.0)	9 (90.0)	8 (80.0)	7 (77.8)	7 (100.0)	9 (90.0)

*10 participants from each site contacted to arrange consent visit from those registered to the trial database, some then excluded at final eligibility check at consent visit

As a feasibility study this trial was not powered to give an indication of sample size for a definitive trial, however, the trial has given the opportunity to consider the numbers of participants that can be recruited to detect a given effect size of the intervention with 5% significance and 90% power. This is discussed in section 8.3.5.

6.3.1 Recruitment rate

The target recruitment rate was 60 participants in ten months. There was an initial delay in receiving HRA approval so sites opening was delayed by one month. Recruitment began in December 2018 with staged opening of sites to allow for capacity within the research team to undertake consent visits. Following the first site, which opened in December 2018, the others followed in pairs (one intervention and one control) leaving one month between openings of sites. Although it had been anticipated that initial identification and screening for each site would take one month to complete, in reality, this process took longer; between one and six months to complete dependent on the site.

The first participant was recruited on 27th February 2019 and, although the trial started later than planned, higher than anticipated recruitment rates were noted across all sites, with an average of 9.3 participants per month achieved (6 participants/month were predicted). Total number of participants recruited per month is shown in Figure 6.2a and number of participants recruited at each site per month is reported in Figure 6.2b.



Figure 6.2a: Participants recruited per month (all sites)

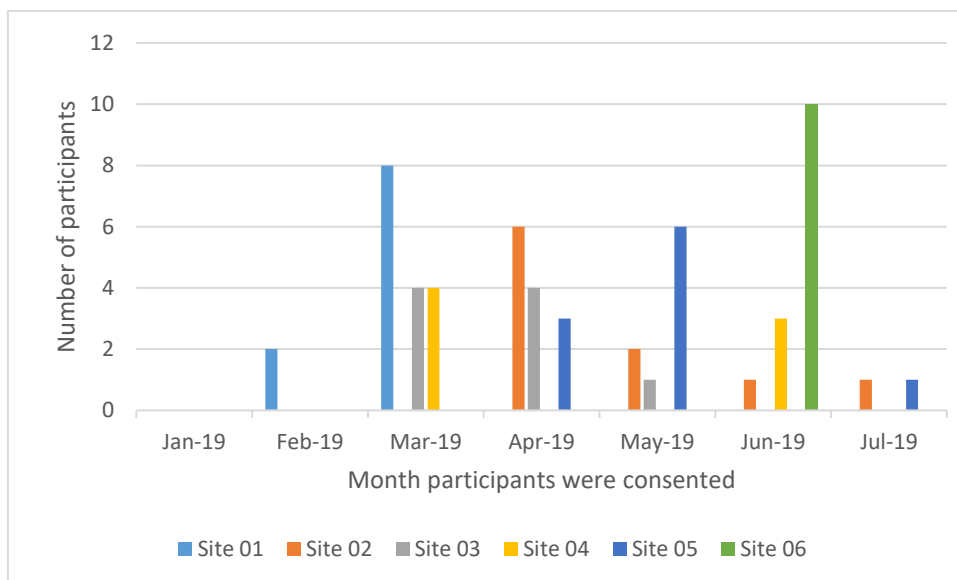


Figure 6.2b: Participants recruited each month (per site)

6.4 Randomisation

Randomisation of clusters was conducted according to the randomisation specification (Appendix 13: Appendix 1 of Statistical Analysis Plan) and occurred as planned, with

three sites (clusters) allocated to the intervention arm of the study and three sites (clusters) to control (usual care).

6.5 Demographic and baseline data

Baseline demographic data is summarised in Table 6.4.

Table 6.4: Baseline demographic data

	Intervention	Control	All
Mean age in years (SD) [range]	80.0 (7.3) [67-95]	85.1 (6.8) [67-100]	82.4 (7.4) [67-100]
Gender n (%)			
Male	15 (50.0)	10 (31.5)	25 (44.6)
Female	15 (50.0)	16 (68.5)	31 (55.4)
Relationship Status n (%)			
Single	1 (3.3)	2 (7.7)	3 (5.4)
Married/civil partnership	19 (63.3)	15 (57.7)	34 (60.6)
Divorced/civil partnership dissolved	2 (6.7)	1 (3.8)	3 (5.4)
Widowed/surviving civil partner	8 (26.7)	8 (30.8)	16 (28.6)
Living arrangements n (%)			
Alone	10 (33.3)	11 (42.4)	21 (37.5)
Spouse/Partner	19 (63.4)	14 (53.8)	33 (59.0)
Parent/s	0 (0.0)	0 (0.0)	0 (0.0)
With children under 18	0 (0.0)	0 (0.0)	0 (0.0)
With children over 18	0 (0.0)	1 (3.8)	1 (1.75)
Other family	1 (3.3)	0 (0.0)	1 (1.75)
Non-family	0 (0.0)	0 (0.0)	0 (0.00)
Frailty Severity n (%)			
Moderately frail	18 (60.0)	18 (69.3)	36 (64.2)
Severely frail	12 (40.0)	7 (26.9)	19 (34.0)
Missing	0 (0.0)	1 (3.8)	1 (1.78)

The mean age of participants was 82.4 years (range 67-100 years). Mean age in the control group (85.1 years; range 67-100 years) was 5.1 years older than in the intervention group (80.0 years; range; 67-95 years). There were more female participants (55.4%) in the trial than male (44.6%). There were equal numbers of male and female in the intervention group with 50% male (n= 15) and more female than male in the control group; 31.5% male (n= 10). The majority of participants lived with a

partner or spouse n=33 (59.0%), however, there was variation between the intervention and control groups (n=19 (63.4%) intervention, n=14 (53.8%) control). Similar proportions of people in the intervention and control groups were moderately frail (n=18 (69.3%) intervention and n=18 (60.0%) control). Overall, there were smaller numbers of severely frail participants recruited (total n=19 (34.0%)), with n=12 (40.0%) in the intervention group and n=7 (26.9%) in the control group.

6.6 Retention and adherence

Participant retention and adherence to the minimum dose of the intervention (defined as one assessment visit and a minimum of two care planning visits) by site are presented in Table 6.5. Retention across all sites was high with n=53 (94.6%) of participants completing three-month follow-up and n=49 (87.5%) completing six-month follow-up. Retention was similar in both groups with 96.7% of intervention participants completing three-month follow-up and 86.7% completing six-month follow-up compared to 92.3% and 88.5% respectively in the control group.

Table 6.5: Participant retention and adherence

	Intervention			Control		
Variable	Site 01	Site 02	Site 05	Site 03	Site 04	Site 06
Number (%) [ratio] of randomised participants who completed three month follow-up	10 (100) [10/10]	10 (100) [10/10]	9 (90.0) [9/10]	8 (88.9) [8/9]	7 (100) [7/7]	9 (90.0) [9/10]
Number (%) (ratio) of randomised participants who completed six month follow-up	9 (90.0) [9/10]	9 90.0) [9/10]	8 (80.0) [8/10]	7 (77.7) [7/9]	7 (100.0) [7/7]	9 (90.0) [9/10]
Number of randomised participants adhering to intervention minimum dose	9	9	8	N/A	N/A	N/A
Number of operational protocol deviations	0	2	1	1	3	0
Number of participant related protocol deviations	1	1	1	0	0	0

Failure to complete three and six-month follow-up was, in all seven cases, due to withdrawal from the trial. All withdrawals were initiated by the individual participant themselves. In four cases, their health had deteriorated and they did not feel able to continue with the commitment of the trial, one participant had too many health-related appointments and did not have time to participate. One participant stated that the community matron did not attend on the agreed date and, consequently, they decided to withdraw and the remaining participant did not give a reason for withdrawal.

6.7 Adherence to the trial protocol

There were three instances of non-compliance with the trial protocol that related to participants. Two of these disclosed to the research team assessors that they were in the intervention group of the study, resulting in the assessor being unblinded to the

allocation of all participants from that site. The other participant-related protocol deviation occurred when there was a delay in carrying out three-month outcome measures assessment; the delay was at the request of the participant.

There were seven operational protocol deviations, which occurred either at a site or within the Clinical Trials Unit. In all cases these were related to procedures within the protocol, including incorrect application of trial eligibility criteria (identification of participants outside of the age range) and not sending stamped addressed envelopes with the invitation letter. A technical problem with the trial database was identified where reminders to sites to submit three and six month outcomes data were not sent out. This was rectified by the Clinical Trials Unit and the data obtained. None of the operational protocol deviations caused significant delay but did require some processes to be completed twice.

Adherence to the intervention was good with n=4 (15.4%) participants receiving less than the minimum intervention dose. Reasons given for not completing the minimum dose included two instances of admission to hospital, one participant away on holiday and, in one case, difficulties contacting the participant.

6.8 Refinement of intervention content

One of the aims of this feasibility study was to further refine and finalise the content of the intervention and to capture which other health and care services are involved as part of the care planning process, to inform a full trial. The frequency of use of each type of assessment in the intervention pack were evaluated (Table 6.6) plus the number and type of referrals to other services made (Table 6.7).

Table 6.6: Frequency of intervention assessment documents used at intervention visit

	Number (n) of assessment tools used at each visit (V) (all participants)						
HAPPI Intervention Assessment Tools	V1	V2	V3	V4	V5	V6	Total
Medication review summary	19	15	13	13	13	9	82
Conversation Guide	22	14	9	10	6	7	68
Clinical Frailty Scale	22	11	7	5	8	8	61
Personalised support plan (1): my medical plan	0	7	9	11	11	12	50
Personalised support plan (2): my wellbeing plan	0	6	8	8	11	11	44
Numeric pain scale	6	7	7	4	6	3	33
Barthel Index	12	5	3	2	4	5	31
Caregiver strain index	6	8	4	4	3	3	28
Pain assessment record	3	6	4	3	4	0	20
Abbey Pain Scale	0	1	1	1	0	0	20
Mental capacity assessment	6	9	3	1	0	0	19
Comprehensive geriatric assessment	5	5	2	0	0	1	13
Malnutrition universal screening tool	4	6	1	0	1	0	12
Treatment escalation plan	1	4	1	2	2	2	12
3-Item loneliness scale	0	6	3	1	2	0	12
Hospital anxiety and depression scale	0	4	1	3	1	2	11
Bowel assessment form	2	4	2	0	1	1	10
Geriatric Depression Score	1	1	3	3	1	1	10
Malnutrition universal screening tool Flowchart	3	3	1	0	1	0	8
Clinical checklist lower urinary tract symptoms	0	2	3	1	1	0	7
Falls Multifactorial risk assessment tool	2	3	1	0	0	0	6
Malnutrition universal screening tool	1	3	1	0	1	0	6
Checklist faecal incontinence	1	2	1	0	1	0	5
Gait Speed Test	0	4	0	0	0	0	4
STOPP-START medication review	1	2	0	0	0	0	3
Self-assessment lower urinary tract symptoms	0	2	1	0	0	0	3
GP assessment of cognition test	0	0	1	1	1	0	3
Bladder diary	0	1	1	0	0	0	2
Fracture risk assessment tool	0	1	0	0	0	0	1
Royal College Physicians bedside vision test	0	1	0	0	0	0	1
Whispered voice test	0	1	0	0	0	0	1
Delirium screening tool	1	0	0	0	0	0	1

A total of 32 assessment tools were included in the intervention pack (Appendix 6) and all of these were used in the course of the intervention but not with all participants

(Table 6.6). The most frequently used assessment tool was the medication review summary (used 82 times). Other most frequently used tools included the conversation guide used (68 times), the clinical frailty scale (used 61 times), and the personalised care plan templates one and two (used 50 and 44 times respectively). All participants completed the intervention with a personalised care and support plan in place that could be used beyond the life of the study to enhance self-management and as an information source for other clinicians involved in the participant's care in future.

Other assessment tools frequently used (used more than 20 times) were those relating to assessment of pain, function and caregiver strain. Assessment tools that were more specific in focus and related to particular health problems or syndromes were used less frequently (less than 20 times). This evaluation of the type and quantity of assessment tools used will be employed to inform the content of the assessment pack for a full trial and is discussed further in section 8.4.3.

All referrals to health and care services across all intervention time points are summarised in Table 6.7. The highest number of referrals (n=31) was to general practitioners, with lesser numbers of referrals to physiotherapy and voluntary services (n=7), dementia services (n=6) and district nurses (n=4). Overall, referrals to other services was lower than anticipated. It was expected that a multidisciplinary approach would be required for the majority of participants, but this did not appear to be the case. Possible reasons for this are discussed in section 8.7.

Table 6.7: Frequency of type of referrals made at intervention time points

	Number (n) of referrals made at each visit (V) (all participants)						
Service referred to	V1	V2	V3	V4	V5	V6	Total
General Practitioner	5	8	7	4	1	6	31
Physiotherapy	1	4	0	0	1	1	7
Voluntary Sector	2	1	1	1	2	0	7
Dementia Services	1	2	1	0	1	1	6
District Nurses	1	1	0	1	1	0	4
Adult Social Care	0	1	0	1	1	0	3
Practice nurse	0	0	1	1	0	1	3
Podiatry	1	1	0	0	0	0	2
Social Prescribing	0	1	0	1	0	0	2
Occupational Therapy	0	0	0	0	1	0	1
Benefits Agency	1	0	0	0	0	0	1
Community Matron	1	0	0	0	0	0	1
Epilepsy Specialist Nurse	1	0	0	0	0	0	1
Community equipment services	0	1	0	0	0	0	1
Respiratory specialist nurse	0	1	0	0	0	0	1
X-ray	1	0	0	0	0	0	1
Surgical appliances	0	0	1	0	0	0	1
Pendant Alarm	0	0	0	1	0	0	1

6.9 Adverse events and serious adverse events

Safety was assessed by comparing the number and nature of serious adverse events (SAEs) and adverse events (AEs) in both the intervention and control group. There were no reported deaths, AEs or SAEs in either the intervention or the control groups throughout the follow-up period. This was an unexpected finding and possible reasons for this are discussed in section 8.2.8.

6.10 Assessment of sample size for the definitive RCT

As stated in the Statistical Analysis Plan (Appendix 13) the calculation of a sample size for the definitive trial must take into account the effects of clustering. In order to assess

the effect of cluster randomisation, the intraclass correlation coefficient (ICC) can be calculated as a measure of relatedness of clustered data, in human studies values are normally between 0.01 and 0.02 (and ICC of 1 indicating all responses are identical). In this trial, ICC was cautiously estimated to be 0.05. In the statistical analysis plan it was agreed that the future definitive trial will aim to test the intervention with 5% significance and 90% power. Assuming an intra-cluster correlation coefficient (ICC) of 0.05 and cluster size of 10 in a future trial (as in this trial), this yields a design effect 1.45. The numbers required to detect a given effect size are summarised in Table 6.8.

Table 6.8: Estimation of numbers required to detect a given effect size

Effect size	Minimum n	Sample size inflated for cluster sizes of 10 patients per practice
0.1	857	1243
0.2	215	312
0.3	96	140
0.4	54	79
0.5	35	51

Based on recruitment data from this fRCT it would seem feasible for a future trial to recruit 200-300 participants in this population and a modest effect size of 0.2 could be detected at 5% significance with 90% power from centres with an ICC of 0.05.

6.11 Assessment of participant-reported outcome measures

Outcome measures within the study were either participant-reported (SF-36; LTC-6; UCLA-3; Barthel Index; EQ-5D-5L) or data supplied by the general practice from the clinical record (date of death; cause of death; number of hospital admissions and readmissions; total number of days spent in hospital; number of prescribed

medications). All participant-reported outcome measures were collected at baseline, three-month and six-month study visits. Data was recorded using case report forms (Appendix 14) and an outcome measure questionnaire (Appendix 15). Feasibility of proposed outcome measures was evaluated with the aim of informing the selection of a primary outcome measure or, potentially, multiple outcomes requiring multivariate analysis within a definitive trial. This feasibility trial gave the opportunity to ascertain, which outcome measures are acceptable to the participants, which can be administered in primary care, and which are sensitive to change at the different time points. This was assessed by reporting of the mean, standard deviation, range, median and interquartile range for each measure at each time point (Table 6.9). In addition, levels of missing data for each outcome measure over time were reported and these are discussed in section 6.11.8. In order to give some indication of sensitivity of outcome measures to change over time, these data are reported with 95% confidence intervals. Each outcome measure was assessed individually and compared against the others for feasibility in terms of completeness, ease of administration and acceptability. This will be considered further in the section 8.3.4.

Table 6.9: Participant-reported outcome measure data

Variable		Intervention Group			Control Group		
Time point		Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks	Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks
SF-36 <i>Physical functioning: Items 3a, 3b, 3c, 3d,3e,3f,3g,3h,3i,3j</i>	Mean (SD) [range] Median (IQR)	305 (242.2) [0-850] 300 (412.5)	292.5 (222.6) [0-850] 250 (350.0)	271.1 (235.4) [0-800] 175 (450.0)	314.1 (275.5) [0-950] 200 (375.0)	297.9 (231.5) [0-900] 300 (337.5)	278.2 (263.2) [0-950] 200 (350.0)
<i>Role-physical: Items 4a,4b,4c,4d</i>	Mean (SD) [range] Median (IQR)	206.7 (132.2) [0-400] 225 (237.5)	180.8 (117.7) [0-350] 175 (206.2)	216.3 (133.2) [0-400] 200 (262.5)	191.4 (148.3) [0-400] 200 (287.5)	183.3 (153.0) [0-400] 162.5 (331.25)	206.5 (142.5) [0-400] 200 (275.0)
<i>Bodily pain: Items 7,8</i>	Mean (SD) [range] Median (IQR)	94.3 (56.0) [0-200] 92.5 (90.0)	85.2 (50.7) [0-200] 70.0 (70.0)	101.0 (60.2) [20-200] 100 (95.0)	119.8 (62.6) [0-200] 132.5 (115.0)	127.9 (68.2) [20-200] 127.5 (135.0)	115.4 (62.7) [20-200] 90 (135.0)
<i>General Health: Items 1,11a,11b,11c,11d</i>	Mean (SD) [range] Median (IQR)	215.8 (105.5) [50-400] 212.5 (187.5)	188.4 (114.9) [25-425] 162.5 (200.0)	187.2 (112.1) [25-425] 155 (115.0)	201.0 (95.8) [25-400] 175 (143.75)	222.8 (101.4) [100-425] 175 (175.0)	211.1 (96.3) [25-375] 200 (137.5)
<i>Vitality: Items 9a,9e,9g,9i</i>	Mean (SD) [range] Median (IQR)	134.5 (69.6) [50-275] 125 (112.5)	127.8 (85.8) [0-300] 100 (150.0)	118.0 (90.3) [0-325] 100 (100.0)	128.8 (67.3) [0-275] 150 (100.0)	138.5 (95.8) [0-325] 112.5 (125.0)	140.2 (83.5) [0-300] 125 (125.0)
<i>Social functioning: Items 6,10</i>	Mean (SD) [range] Median (IQR)	123.3 (73.1) [0-200] 137.5 (150.0)	135.9 (69.0) [50-200] 175.0 (125.0)	103.4 (20.2) [55-175] 105.0 (5.0)	126.9 (58.7) [0-200] 125.0 (81.25)	133.6 (62.3) [5-200] 125.0 (95.0)	85.6 (34.3) [5-125] 100.0 (30.0)
<i>Role-emotional: Items 5a,5b,5c</i>	Mean (SD) [range] Median (IQR)	217.5 (91.5) [75-300] 225.0 (162.5)	228.7 (90.3) [0-300] 300.0 (150.0)	264.4 (57.9) [100-300] 300.0 (75.0)	201.9 (104.4) [0-300] 262.5 (200.0)	204.1 (119.0) [0-300] 287.5 (212.50)	251.0 (70.5) [75-300] 300.0 (75.0)

		Intervention Group			Control Group		
Time point		Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks	Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks
<i>Mental health: Items 9b,9c,9d,9f,9h</i>	Mean (SD) [range] Median (IQR)	348.3 (117.8) [50-475] 375.0 (150.0)	352.7 (104.8) [100-500] 375.0 (150.0)	432.2 (204.0) [250-500] 425.0 (125.0)	367.0 (85.3) [150-475] 400.0 (125.0)	394.8 (81.4) [125-500] 400.0 (93.75)	393.5 (74.7) [200-500] 425.0 (125.0)
<i>Reported health transition: Item 2</i>	Mean (SD) [range] Median (IQR)	36.6 (21.5) [0-75] 37.5 (25.0)	35.2 (18.7) [0-75] 25.0 (25.0)	38.6 (27.9) [5-100] 37.5 (30.0)	33.6 (25.4) [0-100] 25.5 (25.0)	42.7 (23.9) [0-100] 50.0 (25.5)	38.9 (24.7) [5-75] 25.0 (25.0)
LTC-6	Mean (SD) [range] Median (IQR)	9.5 (5.4) [0-18] 8.5 (9.25)	11.5 (5.3) [1-18] 13.0 (8.0)	11.4 (4.7) [2-18] 11.5 (7.5)	12.5 (4.3) [0-18] 13.5 (7.0)	11.7 (6.1) [0-18] 14.0 (10.75)	13.6 (4.3) [2-18] 15.0 (7.0)
UCLA-3	Mean (SD) [range] Median (IQR)	4.6 (2.0) [3-9] 4.0 (3.25)	4.6 (2.1) [3-9] 4.0 (3.25)	4.6 (2.1) [3-9] 4.0 (3.25)	4.2 (1.7) [3-9] 4.0 (1.25)	3.9(1.1) [3-6] 3.0 (2.0)	3.9 (2.1) [3-9] 4.0 (3.25)
Barthel Index	Mean (SD) [range] Median (IQR)	15.8 (2.8) [10-18] 17.0 (4.5)	18.0 (2.5) [11-20] 18.5 (2.0)	17.7 (2.7) [12-20] 19.0 (4.5)	15.5 (2.9) [9-18] 16.5 (4.25)	17.5 (4.2) [4-20] 19.5 (3.0)	17.3 (3.8) [8-20] 19.0 (3.2)
EQ-5D-5L Index Values	Mean (SD) [range] Median (IQR)	0.50 (0.29) [0.19-1.0] 0.55 (0.36)	0.59 (0.24) [0.16-1.0] 0.66 (0.23)	0.58 (0.31) [0.27-1.0] 0.54 (0.41)	0.58 (0.28) [0.10-1.0] 0.66 (0.33)	0.61 (0.26) [0.61-1.0] 0.69 (0.30)	0.64 (0.22) [0.15- 1.0] 0.66 (0.27)
EQ-5D-5L VAS	Mean (SD) [range] Median (IQR)	61.5 (20.8) [20-94] 60.0 (31.0)	59.9 (19.2) [9-90] 60.0 (25.0)	60.1 (19.5) [10-95] 60.0 (26.0)	60.9 (15.3) [35-90] 59.0 (23.0)	64.7 (19.7) [20-100] 65.0 (18.0)	63.0 (19.5) [10-95] 65.0 (25.0)

6.11.1 Assessment of SF-36

Mean scores for all eight health domains of the SF-36 were low across all participants and ranges were wide (Figures 6.3-6.11). Mean scores in the physical functioning domain reduced across the three time points in both groups (Figure 6.3).

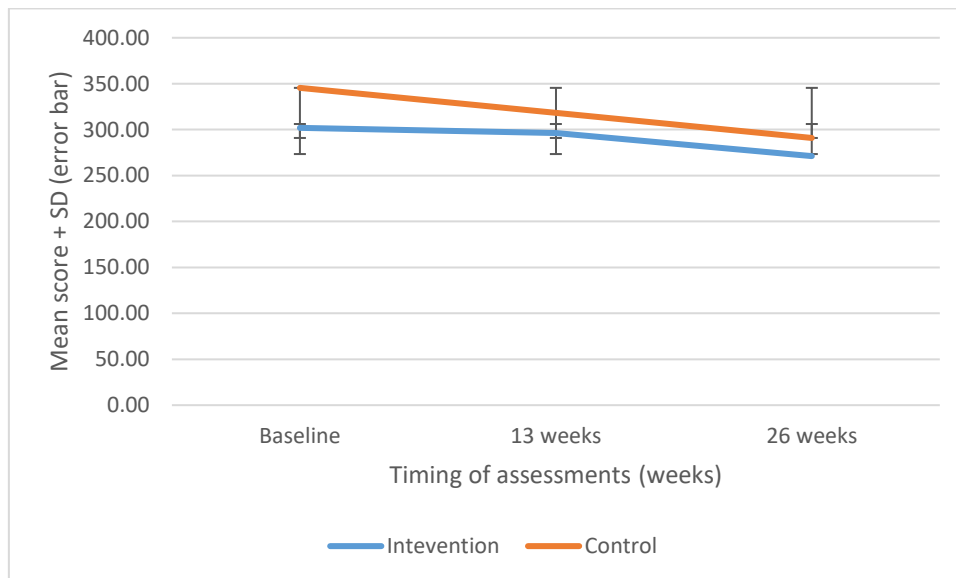


Figure 6.3: Change scores for physical functioning domain (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

In the social functioning domain, mean scores increased in both groups at 13 weeks but fell again at 26 weeks (Figure 6.4).

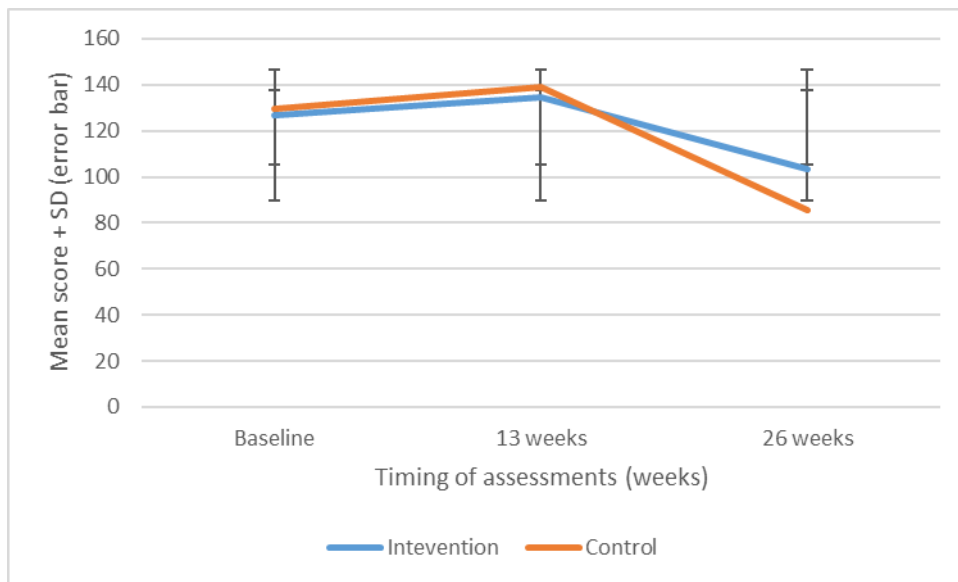


Figure 6.4: Change scores for social functioning domain (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

In the general health domain, scores initially increased at 13 weeks but dropped again to almost baseline levels at 26 weeks in the intervention group. In the control group scores reduced at 13 weeks and although they increased somewhat at 26 weeks, they were not back to baseline. (Figure 6.5).

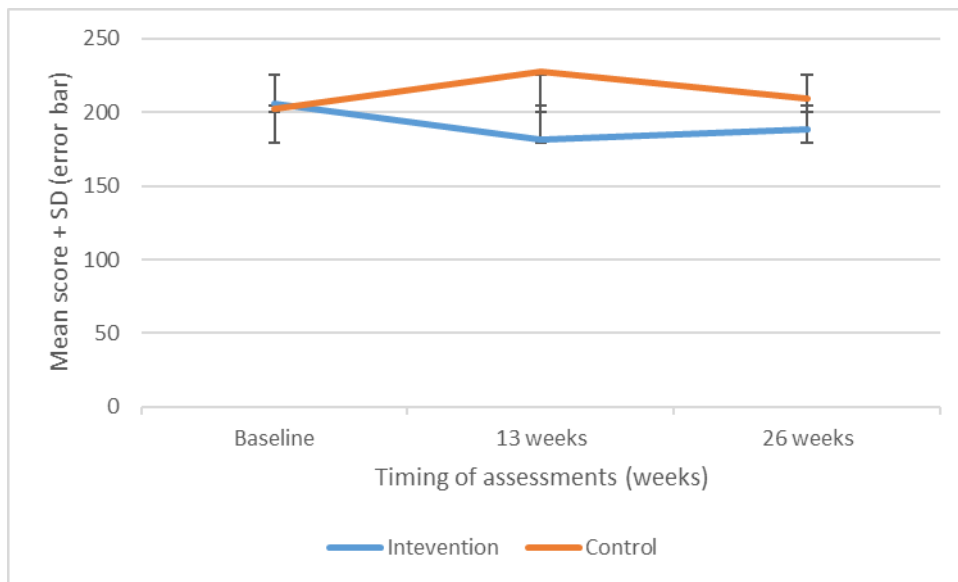


Figure 6.5: Change scores for general health domain (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

Vitality domain scores were higher in the control group than in the intervention across all three time points and they increased at 13 and 26 weeks. Intervention group scores decreased at 13 weeks and 26 weeks (Figure 6.6).

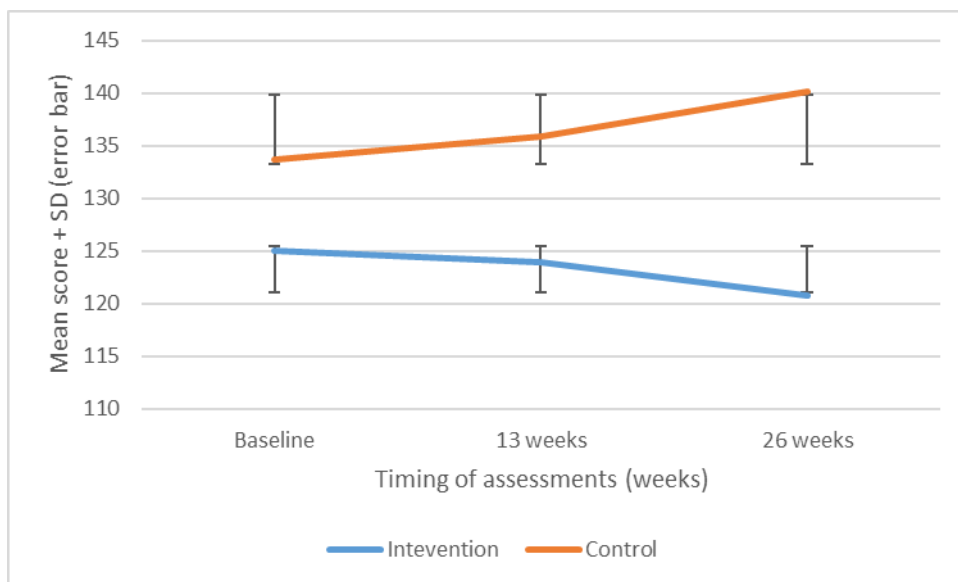


Figure 6.6: Change scores for vitality domain (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

In the role-emotional domain, scores increased in both groups with a larger increase at 26 weeks in the intervention group (Figure 6.7).

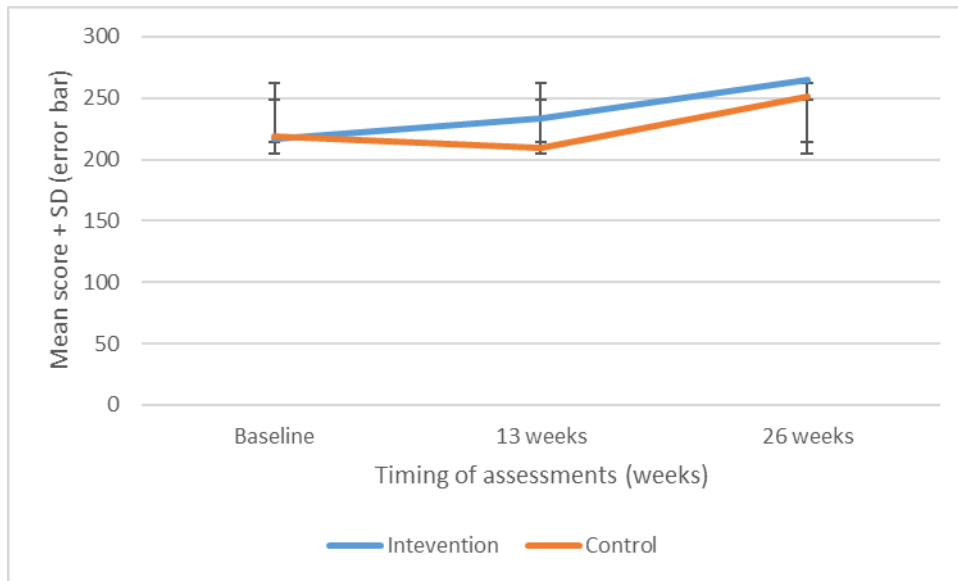


Figure 6.7 Change scores for role-emotional domain (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

Mental health domain scores were initially higher in the control group than in the intervention, however, at 26 weeks, control group scores had decreased, whereas intervention scores were stable at 13 weeks but increased above control group at 26 weeks (Figure 6.8).

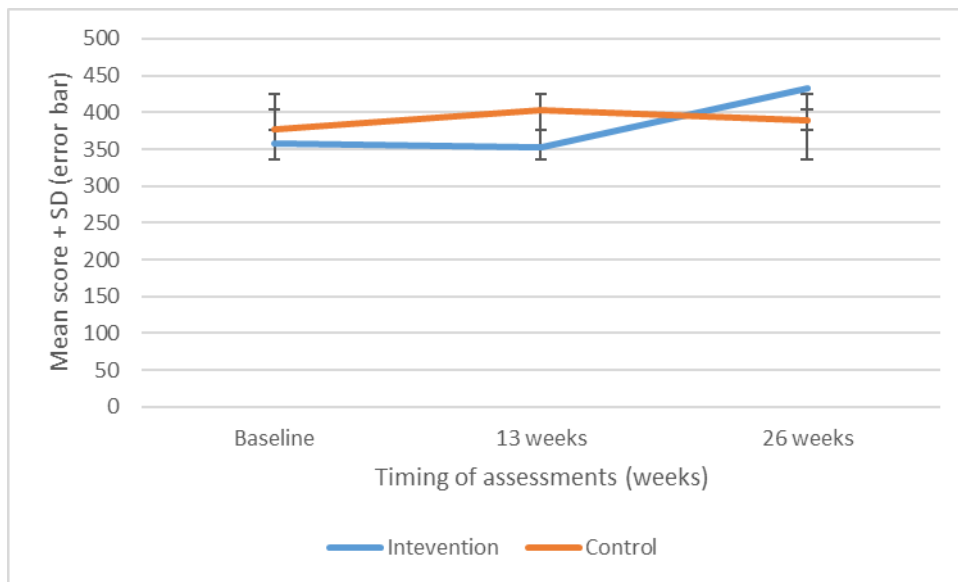


Figure 6.8 Change scores for mental health domain (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

Role-physical domain scores were higher in the control group than in the intervention at baseline, both group scores decreased at 13 weeks and rose again at 26 weeks with the intervention group increasing more. (Figure 6.9).

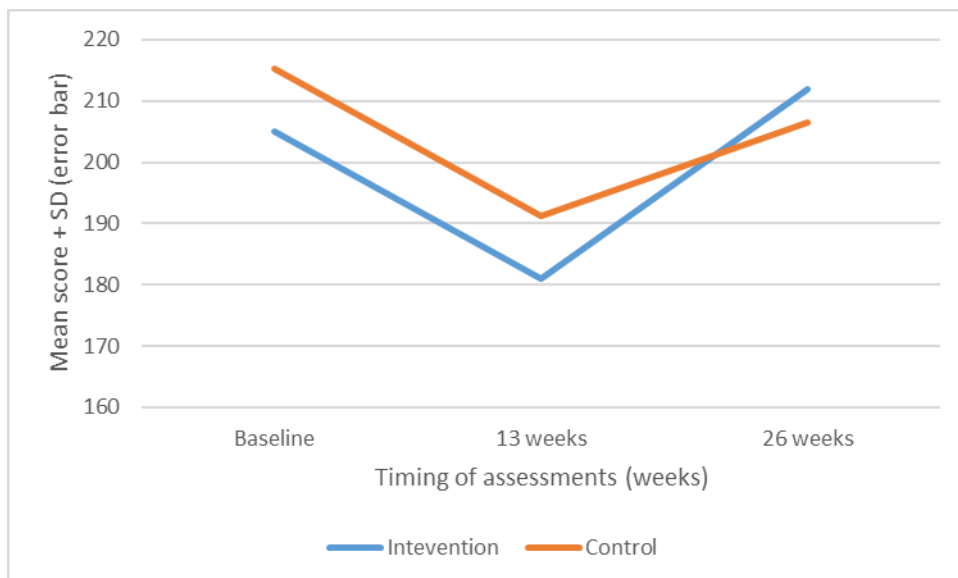


Figure 6.9: Change scores for role-physical domain (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

Bodily pain domain scores were higher in the control than in the intervention group, with the control group scores remaining stable across the three time points. Intervention group scores were also stable at 13 weeks but increased at 26 weeks (Figure 6.10).

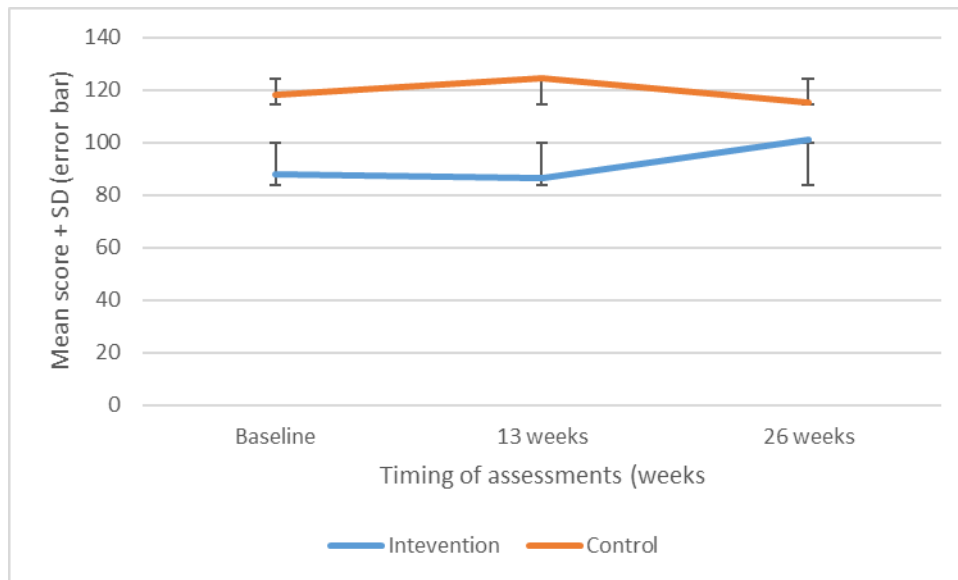


Figure 6.10: Change scores for bodily pain domain (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

In the final item of the SF-36 (Reported Health Transition), participants gave their opinion on whether or not they expected their health to deteriorate. Scores on this domain decreased at 13 weeks in the intervention group but rose above baseline levels at 26 weeks. In the control group, scores rose at 13 weeks but reduced again at 26 weeks, although not back to baseline levels (Figure 6.11).

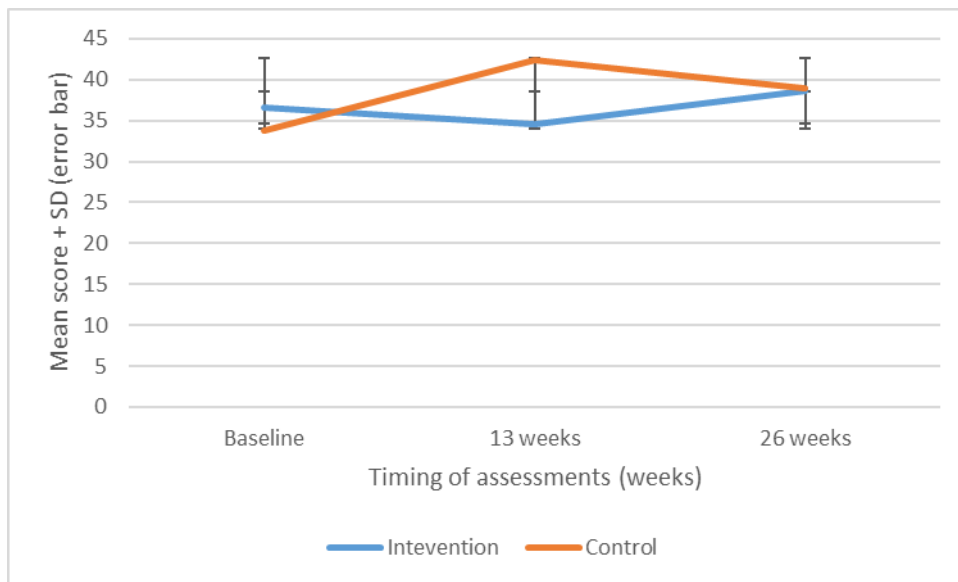


Figure 6.11: Change scores for reported health transition (SF-36) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

6.11.2 Assessment of LTC-6

A higher score in the LTC-6 questionnaire indicates higher levels of confidence in the participant's own ability to self-manage their long term condition and participate in shared decision making. Ranges were wide across all groups at each time point (Table 6.9). Overall scores were lower in the intervention group than in control. Scores rose from baseline at 13 and 26 weeks in the intervention group and did show an increase from baseline at 26 weeks. In the control group scores reduced compared to baseline at 13 weeks, but rose higher than baseline at 26 weeks (Figure 6.12).

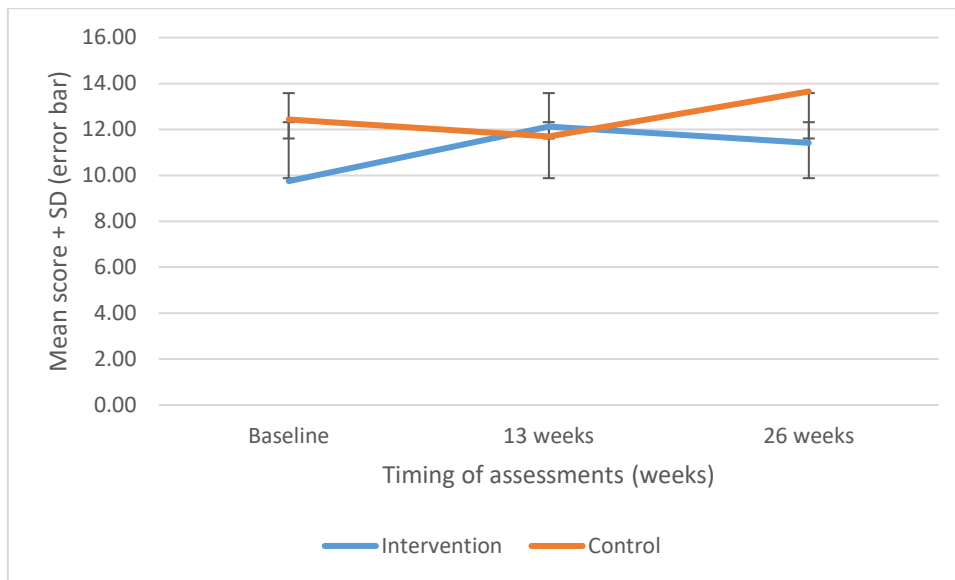


Figure 6.12: Change scores for LTC-6 for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

6.11.3 Assessment of UCLA-3

This three-item questionnaire measures the impact of loneliness for older people, with scores of 2-5 indicating “not lonely”, 6-9 indicating “lonely”. Mean scores remained stable across all time points in the intervention group. Scores in the control group were also relatively stable (Figure 6.13). Overall, across all time points, mean scores were higher in the intervention group than in the control group. The range of scores was large in both groups (Table 6.9).

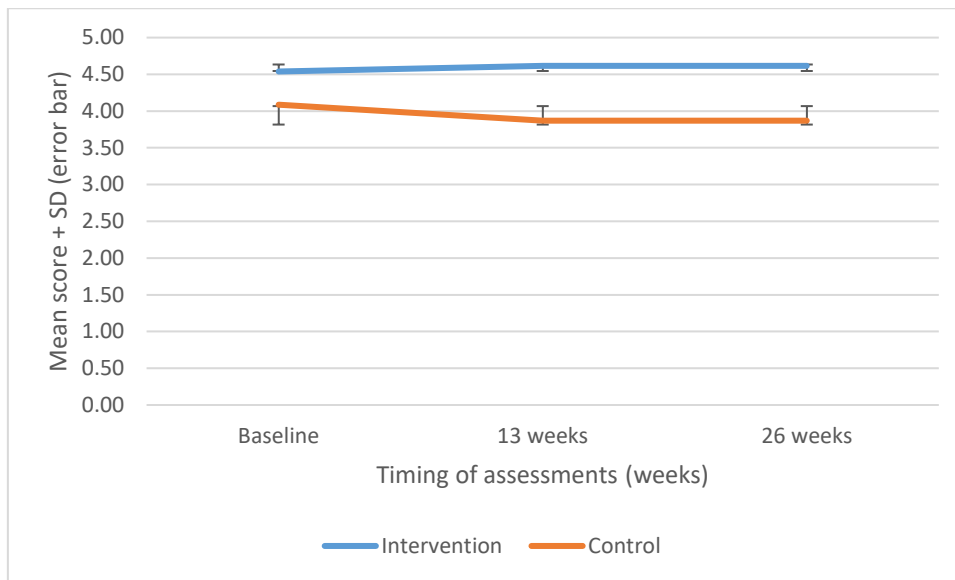


Figure 6.13: Change scores for UCLA-3 for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

6.11.4 Assessment of Barthel Index

The Barthel Index is a ten item questionnaire rating a person's degree of independence in performing functional self-care and mobility activities with lower scores indicating increased disability. Mean scores rose in both groups at 13 weeks then remained stable at 26 weeks in the intervention group. Scores decreased at 26 weeks in the control group (Fig 6.14).

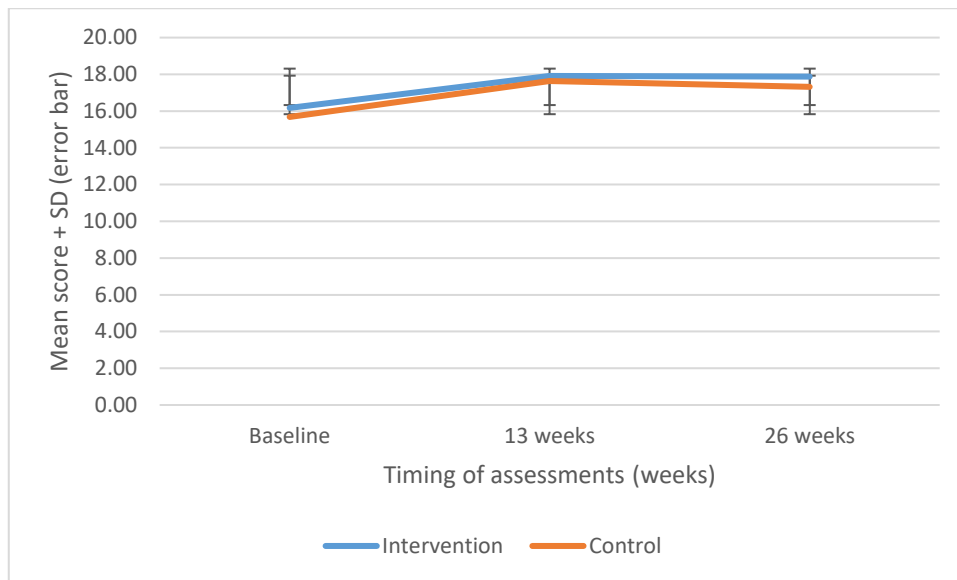


Figure 6.14: Change scores for Barthel Index for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

6.11.5 Assessment of EQ-5D-5L

The EQ-5D-5L is a 25 item descriptive system measuring health status across five health dimensions. In this study, mean scores for index values (Figure 6.15) and VAS (Figure 6.16) as well as frequencies for each level in the five health dimensions (Table 6.10) were generated. EQ-5D-5L descriptive system data were obtained with missing data relating to withdrawals rather than non-completion of questionnaires. In assessing the descriptive system using the five health domains (Table 6.10), the majority of participants recorded high scores in the domains of self-care, mobility, anxiety and depression and usual activity, indicating they experienced either no or slight problems. More participants recorded middle or lower scores in the pain domain, indicating moderate or severe problems.

Table 6.10 EQ-5D-5L descriptive system frequencies across all time points

EQ-5D Dimension n (%)		Intervention Group			Control Group		
		Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks	Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks
Mobility (Levels: 1 no problems 2 slight problems 3 moderate problems 4 severe problems 5 extreme problems)	Level 1	6 (20.0)	5 (16.7)	6 (20.0)	4 (15.4)	5 (19.2)	5 (19.2)
	Level 2	5 (16.6)	5 (16.7)	1 (3.3)	4 (15.4)	7 (26.9)	4 (15.4)
	Level 3	12 (40.0)	10 (33.3)	10 (33.3)	14 (53.8)	6 (23.1)	8 (30.8)
	Level 4	5 (16.7)	5 (16.7)	8 (26.7)	4 (15.4)	6 (23.1)	5 (19.2)
	Level 5	2 (6.7)	1 (3.3)	1 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)
	Missing data	0 (0.0)	1 (3.3)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
Self-care Levels: 1 no problems 2 slight problems 3 moderate problems 4 severe problems 5 extreme problems	Level 1	14 (46.7)	20 (66.7)	10 (33.3)	19 (73.1)	17 (65.4)	12 (46.2)
	Level 2	10 (33.3)	2 (6.7)	10 (33.3)	3 (11.5)	4 (15.4)	6 (23.1)
	Level 3	3 (10.0)	3 (10.0)	5 (16.7)	2 (7.7)	1 (3.8)	4 (15.4)
	Level 4	3 (10.0)	1 (3.3)	0 (0.0)	2 (7.7)	2 (7.7)	1 (3.8)
	Level 5	0 (0.0)	0 (0.0)	1 (3.4)	0 (0.0)	0 (0.0)	0 (0.0)
	Missing data	0 (0.0)	3 (7.7)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
Usual activity Levels: 1 no problems 2 slight problems 3 moderate problems 4 severe problems 5 extreme problems	Level 1	7 (23.3)	5 (16.7)	9 (30.0)	6 (23.1)	11 (42.3)	7 (26.9)
	Level 2	9 (30.0)	11 (36.7)	5 (16.7)	9 (34.6)	6 (23.1)	6 (23.1)
	Level 3	9 (30.0)	6 (20.0)	6 (20.0)	6 (23.1)	3 (11.5)	4 (15.4)
	Level 4	2 (6.7)	3 (10.0)	3 (10.0)	0 (0.0)	3 (11.5)	4 (15.4)

EQ-5D Dimension n (%)		Intervention Group			Control Group		
		Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks	Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks
	Level 5	3 (10.0)	1 (3.3)	3 (10.0)	5 (19.2)	1 (3.8)	2 (7.7)
	Missing data	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
Pain Levels: 1 no problems 2 slight problems 3 moderate problems 4 severe problems 5 extreme problems	Level 1	3 (10.0)	3 (10.0)	8 (26.7)	7 (26.9)	7 (26.9)	7 (26.9)
	Level 2	8 (26.7)	4 (13.3)	2 (6.7)	10 (38.5)	7 (26.9)	4 (15.4)
	Level 3	7 (23.3)	13 (43.3)	9 (30.0)	4 (15.4)	5 (19.2)	11 (42.)
	Level 4	11 (36.7)	5 (16.7)	7 (23.3)	3 (11.5)	3 (11.5)	1 (3.8)
	Level 5	1 (3.3)	1 (3.3)	0 (0.0)	2 (7.7)	2 (7.7)	0 (0.0)
	Missing data	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
Anxiety/depression Levels: 1 no problems 2 slight problems 3 moderate problems 4 severe problems 5 extreme problems	Level 1	15 (50.0)	16 (53.3)	17 (56.7)	14 (53.8)	16 (61.5)	16 (61.5)
	Level 2	8 (26.7)	5 (16.7)	6 (20.0)	8 (30.8)	4 (15.4)	6 (23.1)
	Level 3	5 (16.7)	5 (16.7)	3 (10.0)	3 (11.5)	3 (11.5)	1 (3.8)
	Level 4	2 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	0 (0.0)
	Level 5	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	0 (0.0)	0 (0.0)
	Missing data	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)

Index value scores were lower in the intervention than the control group and both groups scores increased over time (Figure 6.15).

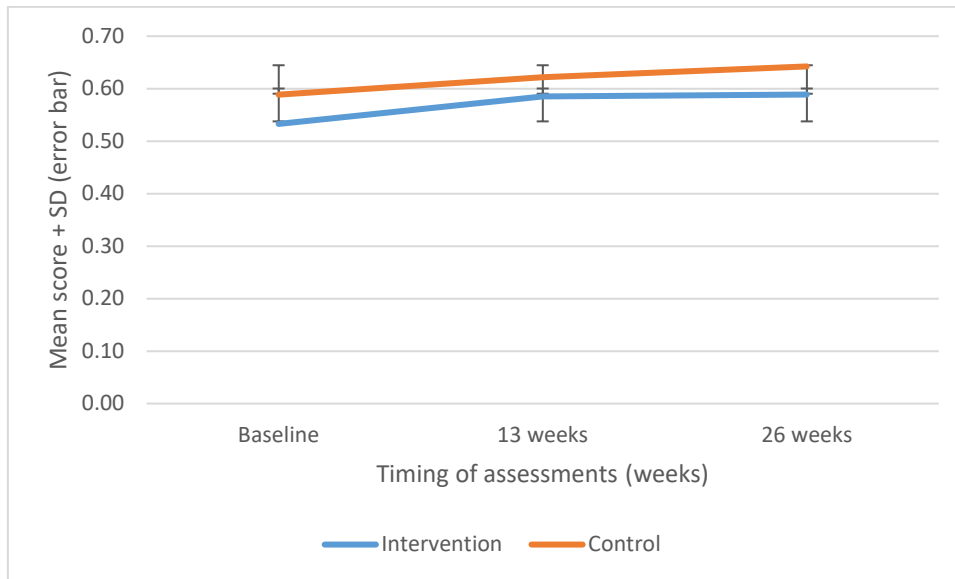


Figure 6.15: Change scores for EQ-5D-5L (Index Values) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

VAS scores were higher at baseline in the intervention group, however, the control group increased above the intervention group at 13 weeks. At 26 weeks, control group scores had fallen and intervention group scores demonstrated a small increase (Fig 6.16).

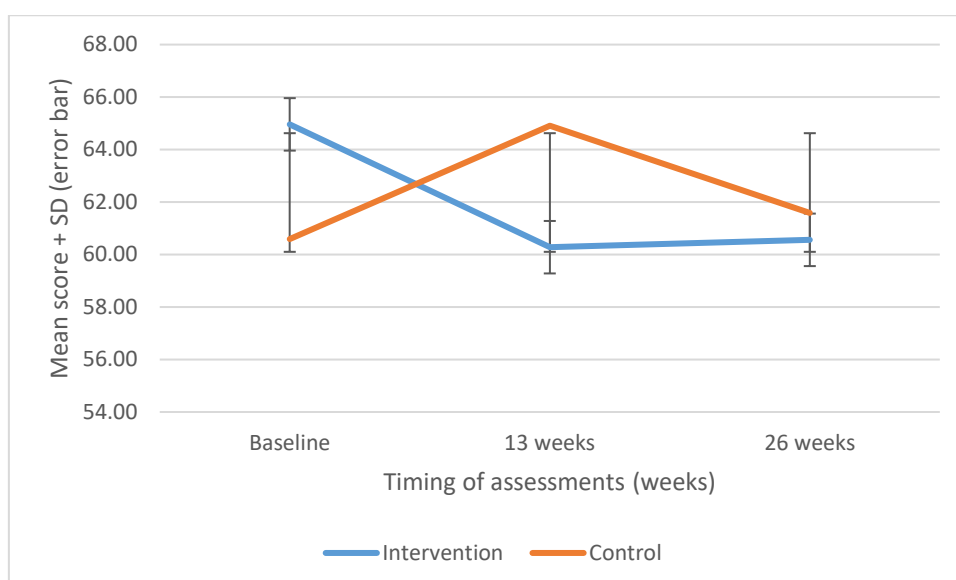


Figure 6.16: Change scores for EQ-5D-5L (VAS) for participants who completed assessments at all time-points in intervention (n=24) and control (n=21) groups

6.11.6 Assessment of site-reported outcome data

Remaining outcome data were obtained from the general practices (sites) and taken from the participant's electronic clinical record (date of death; cause of death; number of hospital admissions and readmissions; total number of days spent in hospital; number of prescribed medications). Mean, standard deviation, range, median and interquartile range for each measure at each time point are reported in Table 6.11.

Table 6.11: Site-reported outcome measures

Variable		Intervention Group			Control Group		
Time point		Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks	Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks
Number of deaths	Mean (SD) [range] Median (IQR)	0.00(0.00) [0-0] 0.00 (0)	0.00(0.00) [0-0] 0.00 (0)	0.00(0.00) [0-0] 0.00 (0)	0.00(0.00) [0-0] 0.00 (0)	0.00(0.00) [0-0] 0.00 (0)	0.00(0.00) [0-0] 0.00 (0)
Number of hospital admissions	Mean (SD) [range] Median (IQR)	0.10 (0.3) [0-1] 0.00 (0)	0.11 (0.3) [0-1] 0.00 (0)	0.15 (0.4) [0-1] 0.00 (0)	0.16 (0.4) [0-1] 0.00 (0)	0.22 (0.5) [0-2] 0.00 (0)	0.39 (0.8) [0-3] 0.00 (1)
Number of hospital readmissions	Mean (SD) [range] Median (IQR)	0.00 (0.0) [0-0] 0.00 (0)	0.00 (0.0) [0-0] 0.00 (0)	0.04 (0.2) [0-1] 0.00 (0)	0.00 (0.0) [0-0] 0.00 (0)	0.00 (0.0) [0-0] 0.00 (0)	0.09 (0.2) [0-1] 0.00 (0)
Total number of days spent in hospital	Mean (SD) [range] Median (IQR)	0.08 (0.3) [0-1] 0.00 (0)	0.31 (1.2) [0-6] 0.00 (0)	0.65 (1.7) [0-1] 0.00 (0)	0.09 (0.3) [0-1] 0.00 (0)	0.23 (0.5) [0-2] 0.00 (0)	3.14 (7.5) [0-28] 0.00 (1)
Number of prescribed medications	Mean (SD) [range] Median (IQR)	11.8 (6.0) [3-31] 10.0 (6)	9.9 (3.62) [5-17] 9.0 (5)	9.3 (3.50) [4-18] 9.0 (5)	10.7 (3.1) [5-16] 11.0 (5)	13.5 (8.2) [6-42] 12.0 (9)	10.6 (3.5) [4-18] 11.0 (5)

There were no reported deaths over the time of the study. Numbers of hospital admissions were lower in the intervention than the control group with one participant in the intervention group admitted at 13 weeks and one at 26 weeks. In the control group there were two admissions at 13 weeks and three at 26 weeks. Readmissions were low in both groups with one readmission in each group at 26 weeks. Days spent in hospital were lower in the intervention than the control group, however, these data should be viewed with caution as one participant experienced a long stay in hospital (28 days). As numbers were low for admissions and readmissions and mean scores were skewed by one participant's data, means were not compared across study time points.

Numbers of prescribed medications were comparable at baseline in intervention and control groups. Numbers increased at 13 weeks in the control group but fell at 26 weeks back to baseline. In the intervention group numbers of medications prescribed decreased at 13 weeks and again at 26 weeks (Figure 6.17).

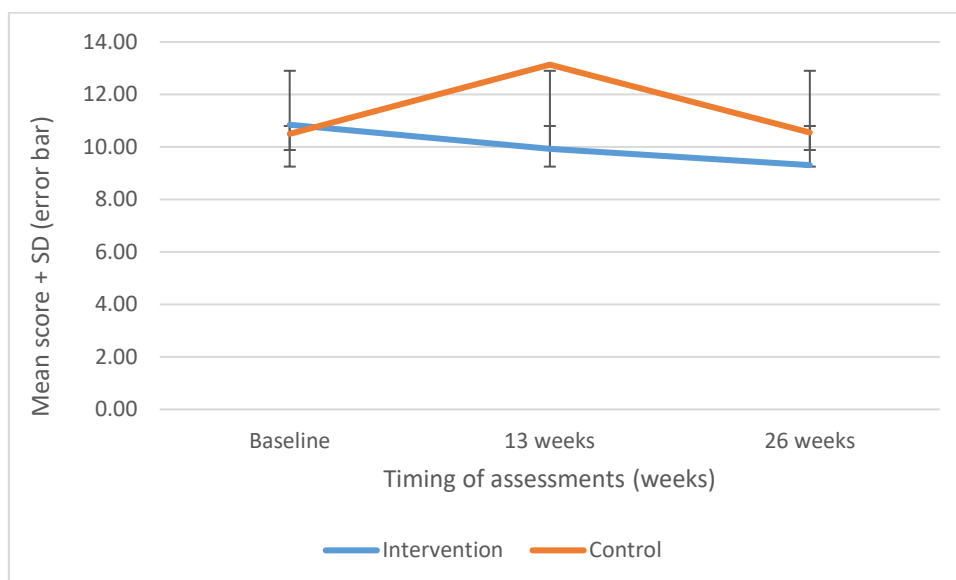


Figure 6.17: Change scores for numbers of prescribed medications at all time-points in intervention (n=26) and control (n=23) groups

6.11.7 Timing of outcome measures assessment

Full details of missing outcome measures are given in the CONSORT diagram (Figure 6.1). All (100%) site-reported CRFs were completed within the trial time scales from all six sites, although in some sites there was a delay in returning the data caused by a database error. Timing of participant reported outcome measures assessments is reported in Table 6.12.

Table 6.12: Timing of outcome measures assessment by group and time point

	Intervention Group (n=) (%)			Control Group (n=) (%)		
	Baseline (n=30)	13 (+/- 1) weeks (n=29)	26 (+/- 1) weeks (n=26)	Baseline (n=26)	13 (+/- 1) weeks (n=24)	26 (+/- 1) weeks (n=23)
Completion status including withdrawals Completed within protocol window (+/- seven days from due date)	30 (100.0)	16 (53.3)	15 (50.0)	26 (100)	10 (38.5)	11 (42.4)
Completed outside of protocol window	0 (0.0)	12 (40.0)	11 (36.7)	0 (0.0)	14 (53.8)	12 (46.1)
Not completed	0 (0.0)	2 (6.7) [n=1 withdrawn] [n= 1 incomplete]	4 (13.3) [n=4 withdrawn]	0 (0.0)	2 (7.7) [n=2 withdrawn]	3 (11.5) [n=3 withdrawn]
Completion status excluding withdrawals Completed within protocol window (+/- seven days from due date)	30(100.0)	16 (55.2)	15 (57.7)	26(100)	10 (41.7)	11 (47.8)
Completed outside of protocol window	0 (0.0)	12 (41.4)	11 (42.3)	0 (0.0)	14 (58.3)	12 (52.2)
Not completed	0 (0.0)	1 (3.4) [n= 1 incomplete]	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

At baseline, n=30 (100%) of outcome measures questionnaires were completed in the intervention group and n=26 (100%) completed in the control group. At 13 weeks, one participant had withdrawn from the intervention group and n=16 (53.3%) questionnaires were completed within the protocol window, at 26 weeks there were three further withdrawals and n=15 (50.0%) were completed within the protocol window out of a possible 30. In the control group, there were two withdrawals at 13 weeks and n=10 (38.5%) were completed within the protocol window, at 26 weeks there had been no further withdrawals and n=11 (42.4%) were completed within the protocol window out of a possible 26.

6.11.8 Assessment of missing outcome data

Completeness of the data is an important feasibility parameter for all outcome measures as it can be used to inform the likely pattern of missing data in a full-scale trial. If a considerable amount of outcome data is missing, this may suggest a need to reconsider the choice of outcome measures and will provide an insight into how missing data can be avoided in the subsequent full trial. The proportion of participants data missing at each outcome are summarised for each allocated group and at each time point (Table 6.13).

Table 6.13: Missing outcome measures by group

Outcome measure	Intervention Group (n=) (%)			Control Group (n=) (%)		
Time point	Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks	Baseline	13 (+/- 1) weeks	26 (+/- 1) weeks
SF-36 <i>Physical functioning</i>	0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	2 (7.7)	3 (11.5)
<i>Role-physical</i>	0 (0.0)	4 (13.3)	4 (13.3)	0 (0.0)	2 (7.7)	2 (7.7)
<i>Bodily pain</i>	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
<i>General Health</i>	0 (0.0)	4 (13.3)	5 (16.7)	0 (0.0)	3 (11.5)	4 (15.4)
<i>Vitality</i>	1 (3.3)	3 (10.0)	5 (16.7)	0 (0.0)	2 (7.7)	3 (11.5)
<i>Social functioning</i>	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
<i>Role-emotional</i>	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
<i>Mental health</i>	0 (0.0)	3 (10.0)	6 (20.0)	1 (3.8)	2 (7.7)	3 (11.5)
<i>Reported health transition</i>	0 (0.0)	3 (10.0)	4 (13.3)	0 (0.0)	2 (7.7)	3 (11.5)
LTC-6	0 (0.0)	3 (10.0)	6 (20.0)	0 (0.0)	2 (7.7)	3 (11.5)
UCLA-3	0 (0.0)	4 (13.3)	4 (13.3)	0 (0.0)	3 (11.5)	3 (11.5)
Barthel Index	1 (3.3)	4 (13.3)	5 (16.7)	0.0 (0.0)	2 (7.7)	4 (15.4)
EQ-5D-5L <i>Mobility</i>	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
<i>Self-care</i>	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
<i>Usual activities</i>	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
<i>Pain/discomfort</i>	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
<i>Anxiety/depression</i>	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	2 (7.7)	3 (11.5)
EQ-5D-5L VAS	0.0 (0.0)	4 (13.3)	4 (13.3)	0.0 (0.0)	3 (11.5)	3 (11.5)
Number of hospital admissions	0.0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	3 (11.5)	3 (11.5)
Number of hospital readmissions	0.0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	3 (11.5)	3 (11.5)
Total number of days spent in hospital	0.0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	3 (11.5)	3 (11.5)
Number of prescribed medications	0.0 (0.0)	3 (10.0)	4 (13.3)	1 (3.8)	3 (11.5)	3 (11.5)

Withdrawals were the main reason for non-completion of participant-reported and site-reported outcome measures at 13 and 24 weeks. The LTC-6 was not fully completed by two participants in addition to those who had withdrawn at 24 weeks. The blinded assessors and administrators were not formally asked to record reasons for non-completion, so these were not captured.

6.11.9 Assessment of responsiveness of proposed outcome measures

Findings presented here relating to responsiveness over time should be interpreted with caution because this feasibility trial was not powered for this purpose.

In order to ascertain which statistical methods should be used to assess change over time, outcome measures data were tested for normality. A visual inspection of histograms and box plots was completed, skewness, kurtosis and z-values calculated for data obtained from all outcome measures. These data are presented in Tables 1-6 in Appendix 16. Mean scores and mean difference are reported with 95% confidence intervals (Table 6.13) for all outcome measures for the intervention and control groups at 26 weeks. Based on these findings and findings from the qualitative study, identification of primary outcome measure for a future trial is discussed in section 7.3.4.

Table 6.14: Mean difference with 95% confidence intervals for intervention and control

groups at week 26

Variable	n; mean (SD)		Mean difference (95% CI)
	Intervention	Control	
SF-36			
Physical functioning	26; 271.15 (235.45)	23; 278.26 (263.21)	-7.11 (-150.4, 136.2)
Role-physical	26; 216.35 (133.22)	23; 206.52 (142.47)	9.82 (-69.4, 89.1)
Bodily pain	26; 100.96 (60.18)	23; 115.43 (62.70)	-14.47 (-49.8, 20.9)
General Health	25; 187.20 (112.14)	22; 211.14 (96.30)	-23.93 (-85.8, 37.9)
Vitality	25; 118.00 (90.29)	23 140.22 (83.51)	-22.23 (-72.9, 28.4)
Social functioning	26; 103.46 (20.14)	23; 85.65 (34.29)	17.81 (1.87, 33.7)
Role-emotional	26; 264.42 (57.95)	23; 251.09 (70.50)	13.34 (-23.6, 50.2)
Mental health	24; 432.25 (204.04)	23; 393.48 (74.70)	38.77 (-52.2, 129.8)
Reported health transition	26; 38.65 (27.88)	23; 38.91 (24.68)	-.259 (-15.5, 15.0)
LTC-6	24; 11.42 (4.66)	23; 13.65 (4.31)	-2.24 (-4.8, .41)
UCLA-3	26; 4.62 (2.16)	23; 3.87 (1.14)	.75 (-.24, 1.73)
Barthel Index	25; 17.72 (2.72)	22; 17.32 (3.83)	.40 (-1.53, 2.34)
EQ-5D-5L Index Values	26; .58 (.31)	22; .64 (.22)	-.07 (-.22, .09)
EQ-5D-5L VAS	26; 60.15 (22.93)	23; 63.04 (19.52)	-2.89 (-15.22, 9.44)
Number of hospital admissions	26; .15 (.37)	23; .39 (.78)	-.23 (-.58, .11)
Number of hospital readmissions	26; .04 (.196)	23; .09 (.29)	-.05 (-.19, .09)
Total number of days spent in hospital	26; .65 (1.72)	23; 3.00 (7.37)	-2.35 (-5.59, .89)
Number of prescribed medications	26; 9.31 (3.51)	23; 10.61 (3.51)	-1.30 (-3.32, .72)

6.12 Feasibility objectives

The feasibility objectives have been evaluated and results relating to each objective are reported in Table 6.15. A number of these objectives were judged by the Trial Management Group and Trial Steering Committee as essential to the success of the study and would be used as criteria to evaluate progression to a full trial or not. These are specifically reported on in section 6.13.

Table 6.15: Feasibility Objectives

Objective summary	Outcome Measures	Study results	Feasible (Y/N)	Suggested Modification
Feasibility of the intervention	Number of consented participants randomised to the intervention group who do not withdraw or die within the intervention period engaging with the minimum “dose” of the intervention.	86.6% of consented participants randomised to the intervention group completed the minimum “dose” of the intervention.	Y	
	Assessment of number of community matrons moving between intervention and control sites	100% (n=5) of community matrons remained with specified site until study completion.	Y	
Feasibility of trial procedures including site feasibility, recruitment and retention	Number of general practices expressing an interest in participating from those approached	14 general practices were approached, 57.1% (n=8) met eligibility criteria.	Y	In a larger trial, a more systematic way of approaching general practices and publicising the study would be employed using Clinical Research and Primary Care Networks.
	Number of general practices approached that participated.	42.8% (n=6) progressed to participation in the trial.	Y	
	Number of general practices screened for selection and reasons for non-selection.	57.1% (n=8) general practices met eligibility criteria. Reasons for non-selection of practices included no community matron in post or did not have the eFI integrated into the electronic clinical notes system.	Y	
	Number of general practices withdrawing from the study, timing and reason for withdrawal.	0% (n=0) general practices withdrew from the study.	Y	

	Outcome Measures	Study results	Feasible (Y/N)	Suggested Modification
	Number of general practices failing to progress through implementation milestones and reasons for failure.	16.7% (n=1) general practice did not complete screening/eligibility processes within prescribed timescale (6 months from site initiation). Others needed significant support to achieve milestones.	Y	Consider how support can be provided to sites in completing study processes in a timely manner through Clinical Research Network staff or dedicated research assistants.
	Number of general practices withdrawing during the implementation and delivery phases.	0% (n=0) of general practices withdrew during the implementation and delivery phases.	Y	
	Numbers of participants identified using the electronic frailty index (eFI) as a denominator for number of those identified that are eligible.	414 participants identified using the eFI. 21.49% (89) participants were eligible on screening.	N	Review the use of eFI as the sole method of identifying potential participants. Consider how many patients would have to be identified in order to achieve final number of participants in a larger trial.
	Numbers of participants screened as eligible, recruited, consented and followed up	21.49% (n=89) participants eligible on screening, further 8.9% (n=10) found to be ineligible at consent visit. n=56 participants consented. 92.86% (n=52) completed three month follow up. 87.5% (n=49) completed six month follow up.	Y	
	Follow-up rate was predicted to be 70%, with full outcome data on a minimum of 42 participants.	Follow up rate was 87.5% with full outcome data completed on 49 participants.	Y	
	Number of and timing of participant withdrawals from follow-up data collection, reasons for withdrawal, number of and timing of losses to follow-up.	Intervention group: n=1 withdrawal following baseline, n=3 withdrawals at 6 months. Control: n=2 withdrawals following baseline, n=1 withdrawal at 6 months. Overall lost to follow up n=7 (12.5%).	Y	

	Outcome Measures	Study results	Feasible (Y/N)	Suggested Modification
Assessing different potential primary and secondary outcomes of the future trial	Numbers of potential primary and secondary outcome measures completed at baseline and follow-up intervals.	As above, all outcome measures completed unless participant withdrew.	Y	
	Numbers of missing items for each potential primary and secondary outcome at each time-point.	Overall, outcome measures showed high levels of completeness with the exception of LTC-6 which was not fully completed by two participants in addition to those who had withdrawn.	Y	
	Assessment of the feasibility of collecting data to estimate cost-effectiveness using the EQ-5D-5L	EQ-5D-5L showed high levels of completeness in both groups. Data analysed for descriptive system, index values and VAS. This can be used to estimate cost effectiveness in a future trial.	Y	

6.13 Progression to a full trial

Decision on progression to a full trial was based on quantitative data from this fRCT combined with data from the embedded qualitative study and this will be discussed further in Chapter Seven. In relation to quantitative data, criteria for progression was set out in the Statistical Analysis Plan (Appendix 13). Progression to a full trial would be considered viable if certain pre-specified feasibility criteria were met or if clear strategies were identified that could support the delivery of the full trial in tandem with successfully identifying a suitable primary outcome. The success criteria are listed in Table 6.15 and denoted against the following traffic light criteria (Battle *et al.*, 2019).

- Green indicates the target was achieved
- Amber indicates the target was not achieved but progression to full trial would be possible with minor protocol amendments
- Red indicates the target was not achieved and progression to full trial is unlikely to be supported

All feasibility criteria were achieved (green) (Table 6.16) relating to site and participant recruitment, completion of outcome measures and engagement with the intervention. Of the general practice sites who were initially approached, 74% progressed to participation in the study and the target number of sites (n=6) was achieved. Almost all the participant recruitment target was achieved (93%, 56 participants out of the predicted 60) within the 43 week recruitment window. Similar figures were noted for participants who completed three-month outcome measures (92.85%) and 87.5% completed six-month follow up. 85.5% of consented participants completed at least the minimum dose of the intervention. The results of these feasibility criteria were

combined with data on selection of a primary outcome in order to consider progression to a full trial and this will be discussed section 7.6

Table 6.16: Feasibility success criteria results

Feasibility success criteria	Green	Amber	Red	Trial Results
% of general practice sites that were initially approached and progressed to participating in the study	≥ 50%	41-49%	≤ 40%	75.0%
% of recruitment target achieved (60 participants) in the timescale of 43 weeks (01/11/2018-31/08/2019)	≥50%	41-49%	≤40%	93.3%
% of participants completing 3 month follow up	≥80%	51-79%	≤50%	92.85%
% of participants completing 5 month follow up	≥70%	51-59%	≤50%	87.5%
% of consented participants randomised to the intervention group who do not withdraw or die within the intervention period engaging with the minimum “dose” of the intervention	≥75%	51-74%	≤50%	85.5%

Chapter 7: Embedded qualitative study findings

This section presents data gained from interviews with trial participants, carers, community matrons and general practice administrators to gain their views on feasibility of trial processes and acceptability of the intervention.

7.1 Aim of qualitative component

The aim of the qualitative study was to explore the experience of the HAPPI intervention and related trial processes from the perspectives of the participants, carers, community matrons who delivered the intervention and administrators who carried out participant identification, eligibility screening and provision of outcome data. Its purpose was to identify what went well and any barriers to trial implementation with the aim of resolving issues and making improvements to maximise success of a subsequent definitive trial.

7.2 Data Collection

A total of sixteen interviews were conducted guided by the interview topic guides (Appendix 17). These included six trial participants, four from the intervention arm and two from the control arm as per the study protocol. Two carers of participants in the intervention arm were interviewed. It was planned to interview two carers of participants in the control arm, but this proved impossible to achieve because the research team had no way of determining if control participants required carer support.

All five community matrons who delivered the intervention were interviewed and three administrators. It had been planned to interview four administrators, but it proved difficult to access and agree times to interview them. In addition, interviews with two people who declined to participate at the outset, and two people who withdrew from the study were planned, however, the CI was unable to achieve this despite contacting

some decliners and those who withdrew. Individuals had declined or withdrawn due to deterioration in their health and, consequently, did not feel able to participate in an interview. All participant and carer interviews were conducted at their place of residence and community matrons and administrators interviewed at their places of work.

7.3 Data analysis

Data analysis began during transcription of interview data as the start of the interpretative process. The researcher conducted and transcribed all interviews and field notes were written for context, taking account of non-verbal communication, interruptions and the researcher's reflections on the experience. Inductive analysis was used to understand the opinions and experiences of those involved in the study without the researcher's personal views, or those of the literature, intruding. Glaser and Strauss note that the inductive approach limits researchers from inaccurately imposing a predetermined result as codes are initially literal and verbatim drawn directly from the data set (Glaser & Strauss, 1967). The aim was to prioritise the participant voice and so terms used by the participants themselves were presented verbatim in initial coding.

This approach is based in "Grounded Theory" (Glaser & Strauss, 1967, p.233). Whilst wishing to be open to the true meanings of the data collected, it is recognised that the research objectives will have influence and may form a priori categories into which to "fit" the data. Saldana proposes that qualitative coding happens through an analytic lens and that all researchers wear different filters on the lens, which in turn affects perception and interpretation of the data (Saldaña, 2016). The researcher's perspective in this case was to be reflexive, recognise that there are preconceptions, but that these preconceptions will only translate into emerging themes if they are truly supported by

the data. Themes were largely semantic in nature, that is to say, descriptive with an attempt to interpret and theorise significance (Braun & Clarke, 2006).

Thematic analysis was used as a framework to analyse the data. (Braun & Clarke, 2006). After transcription, the interviews were uploaded to the qualitative analysis program NVivo. There then followed thorough reading and familiarisation with the data, with an initial list of aspects that appeared interesting highlighting relevant text extracts. A first cycle coding process was completed to generate initial codes, these were then transferred to a mind map using the “One Sheet of Paper (OSOP)” method (Ziebland & McPherson, 2006). This enabled generation of second cycle codes and some candidate categories and these were checked back to ensure they were genuinely supported by the data.

Throughout the process a code book was completed with a detailed description of the content of each code. At this stage the emerging codes and categories were discussed with a supervisor. A fellow PhD student then coded a sample of transcripts and reviewed the candidate codes and categories to provide verification and to identify any that had been missed. In order to guide this process a Code to Theory Model was developed (Saldaña, 2016) and further supervisor support sought to identify relationships between codes, categories and to recognise emerging themes. In addition, the results of the data analysis were presented to fellow PhD students and the Trial Management Group to check and verify themes.

It was not part of the original qualitative study protocol to use case study methodology, however, during interviews with community matrons they gave interesting examples to illustrate the impact of the intervention. After discussion with supervisors, it was decided this presented the opportunity to recount one trial participant story as an in-depth case study in order to explore the intervention and its implementation in real life

context. Case study research methods can be used to answer “how” and “why” questions (Yin, 2018, p.23), in this case “How can the intervention be implemented?” and “Why is this likely to be effective for this group of participants?”. The story, as told by the community matron was analysed using narrative analysis to make sense of the story and offer insight into the lived experience (Braun & Clarke, 2013).

7.4 Participant Characteristics

All interview participant names have been replaced with a participant identifier to ensure confidentiality is maintained. Places of work of the community matrons and administrators have not been included as this could lead to identification given the small number of participants and sites/clusters.

Trial participants’ ages ranged from 75-87 years, they were all retired. None had communication difficulties, however, four participants displayed some cognitive impairment and had difficulties recalling some aspects of participation in the study. Five trial participants were moderately frail and one was severely frail. Table 7.1 provides trial participants’ characteristics. It may be that those who were severely frail were less likely to consent to an interview and this led to an imbalance in numbers within each frailty category.

Table 7.1: Trial participant characteristics

Participant identifier	Gender	Age in years	Frailty severity (eFI score)	Group Allocation
P1	Male	75	Severe (0.35)	Intervention
P2	Male	79	Moderate (0.28)	Control
P3	Female	87	Moderate (0.25)	Control
P4	Female	79	Moderate (0.33)	Intervention
P5	Male	78	Moderate (0.28)	Intervention
P5	Female	75	Moderate (0.33)	Intervention

There was one female and one male carer who were identified as C1 and C2. All community matrons were female and administrators were two female and one male. Community matrons were identified as CM1, CM2, CM3, CM4, and CM5. General practice administrators were identified as GPA1, GPA2 and GPA3.

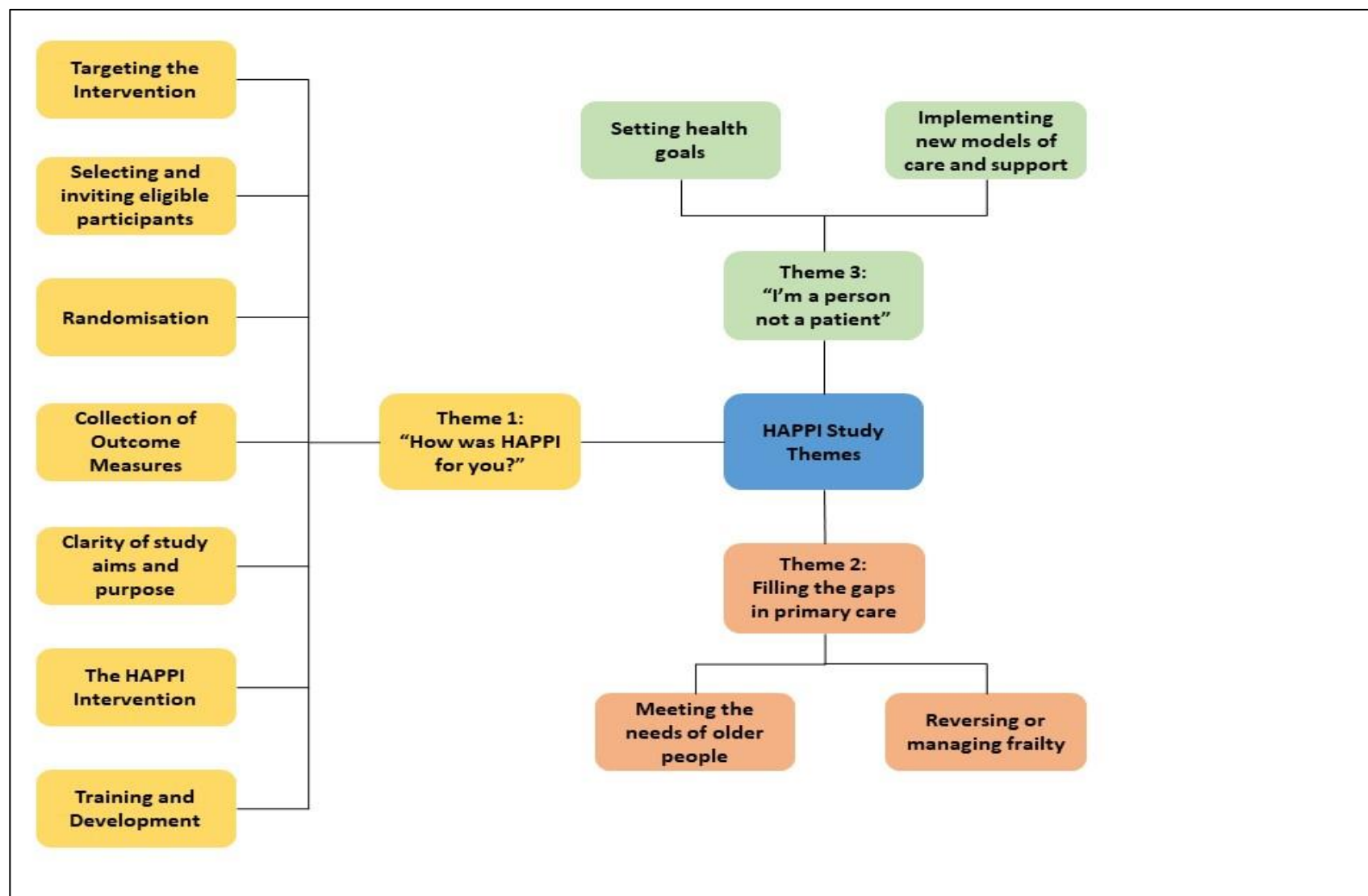
7.5 Themes

Three main themes and twelve sub-themes were identified from the data; these do reflect the research objectives but are expressed here primarily in language that was captured directly from interview data:

- i. “How was HAPPI for you?": Experiences of trial procedures
- ii. “Filling the gaps”: Impact of the intervention
- iii. “I’m a person, not a patient”: The challenges of shared decision making

Figure 7.1 maps the themes and sub-themes and these will be discussed in detail in forthcoming sections of this chapter.

Figure 7.1: Diagrammatical representation of themes



7.5.1 Theme 1: “How was HAPPI for you?”

This theme captures the experiences of participants, carers, community matrons and general practice administrators in participating in and implementing trial procedures and is sub-divided into seven sub-themes.

7.5.1.1 Sub-theme: *Targeting the Intervention*

Existing research indicates that CGA-based interventions may be more effective when aimed at those who are moderately or severely frail (Stuck, 1997). In order to take a systematic approach to identifying moderately or severely frail people, this study used the electronic frailty index (eFI) with verification of diagnosis by PRISMA-7 questionnaire. As one of the first studies to use this method of identification, it was important to understand if this was an achievable selection method in primary care and an effective way of identifying appropriate participants to inform selection for a definitive trial. Administrators reported that the eFI was easy to run as a computerised database search and patient-reporting of the PRISMA-7, as part of an invitation to participate, was not onerous to implement.

“Em, I want to say it was extremely easy, I haven’t changed my mind about it. So, that point in particular was relatively easy for me to do, almost press the button and up popped the names, so that was good” (GPA1)

“No, apart from until we actually started I didn’t know it even existed (Laughs), yeah so actually it’s helped us. It’s already populated to its just narrowing it down to the ones you actually want” (GPA3)

There were, however, some concerns about validity of the results generated by the eFI with an expectation that additional people would be identified as moderately or severely frail and thus administrators did not always agree with the classification.

“I am not sure I quite understand how some of the people end up on (eFI list) be they severe, or moderate or whatever, because I look at some of the names of some of the people I have known for a long time within the practice, and I think I’m not sure you really fit that, but obviously, the computer has been set to pick up the criteria and it has done that thing and we go with it” (GPA1)

"I think I was a little bit surprised by the lists to be honest, the severely frail, I thought I would know more of them and I didn't and I don't know why I've missed them or they haven't come up, em, the moderately frail, I guess we don't see them as much" (GPA2)

Community matrons also had mixed views about the validity of results from eFI, since the eFI classification did not always match the clinical assessment of frailty severity, which would have categorised participants as less frail than eFI scores indicated, and as compared to their usual patients.

"They probably would have been moderately and severely frail but they were the well, they were all much better than my usual patients" (CM3)

"...and sometimes I think I'm trying to work out how they would have come up, you know, as moderate or severe, no I don't feel that any of the three of them were moderate to severe" (CM4)

"I think the classification was right but it took me a while to re-gear from severe to moderate" (CM1)

Community matrons did highlight, nonetheless, that these patients had complex, multiple health problems but had well-developed compensatory mechanisms and so may have appeared to be less frail on first assessment than they actually were.

"Yes and some of them were quite elderly, em, but they had taken quite a responsibility in their own health, they had engaged with, not with my services, but they had engaged with rehab, they were much fitter than patients I would usually see" (CM3)

"She would have been on the higher side of frailty, with her condition she would have sat there, but actually physically, if she hadn't lost weight I think she was compensating and managing really well" (CM5)

eFI was judged to be an effective method of identifying people at the latter stages of the frailty trajectory but before they present in crisis, enabling a more preventative approach to be taken. When asked if they thought there might be a more effective way of identifying participants for the study, the community matrons suggested that a clinical assessment, or triage, by someone who knew the patient well might present a more accurate picture of frailty severity.

"I think it's about your perception of frailty still, I think there's still an issue with that, a scoring system is still different from a visual isn't it?" (CM2)

“No, it’s about knowledge really isn’t it and physically the GPs having to think, well I saw that patient and I’ve looked” (CM5)

“We go out and triage them now because we can’t tell on paper if this is how they really are and we are trialling that at the minute so I don’t know, because you can’t do everybody, you couldn’t but you have to have a guide, so if that’s the guide it may be that you need to look at a higher score?” (CM5)

It was acknowledged that clinical assessment or even triage might be problematic to achieve in practice in terms of resources but also in making an objective judgement.

This is corroborated by Fougère et al who concluded from their cross-sectional study that clinical “impression” of frailty is not as effective in making a diagnosis as using an objective frailty screening tool (Fougère et al., 2017).

7.5.1.2 Sub-theme: Selecting and inviting eligible participants

This part of the recruitment process was primarily the responsibility of administrators who, following random sampling of eFI patient lists, sent invitation letters, collated responses and completed the trial screening log. If there were inadequate responses to the letter then the administrators made follow-up phone calls to ensure the patients had received the information and invite them again to participate. The process for sending, receiving and processing replies was reported as straightforward and related trial procedures were followed without difficulty. Numbers involved were relatively small so this was not perceived to be an onerous task.

“I think I accepted that as being a necessary part of what we were doing, there was no other way around it other than to prepare the letters, you have to merge and send, sign them off and send them off, it wasn’t that difficult, em, just part of it” (GPA1)

“That was simple, I kept a list of all the people that was sent the letters out to and as they came back I basically just used a highlighter with yellow for the nos and the yeses in green. Simple as that really and then I obviously kept the replies and lists of when we heard back from them” (GPA3)

Some mistakes had occurred within the initial identification and invitation process and this led to the need to repeat some actions.

"I think, what I normally do is make up set searches for each of the criteria and then I join all the searches together so that it brings them all together, but then I forgot one of the searches (laughs), that was my issue" (GPA3)

"I tried to do it on Docman as we generally use Docman to send letters to patients, but I forgot the second part of the letter, so I had to send it twice, so... only my own silly mistakes really" (GPA3)

Instructions for completion of the screening log were thought to be ambiguous and this led to some errors, which were addressed in consultation with the CI.

"I thought that meant I had done my bit and it was over, but that's not what it meant... yeah, because once you explained it I got it, but I had translated it in a completely different way" (GPA2)

Some administrators felt uncomfortable making the follow-up phone calls as they did not want to be seen to be persuading people to participate when they did not want to. Some aggression was experienced from a few people who did not wish to be involved and so did not respond to the letter. Consequently, they were not happy to be asked again in a phone call. This was a small minority of patients and most were pleased to be asked to participate, even if they chose not to.

(Laughs) "...em, yes, but in the main it was people, basically, their failure to respond was that they didn't want to be involved, so being asked again on a follow-up phone call, they weren't very pleased about that either. This is something we find in a lot of other instances where you are trying to invite people, they won't respond to say, thank you but no, their inner thought is, "I'm not responding, I don't want to get involved so I won't respond" (GPA1)

Eligibility criteria relating to age and living at home were considered to be clear and unambiguous and could be applied using information taken from the clinical record. It was difficult, at times, to establish mental capacity from the clinical record as often this was not formally recorded. One administrator who had a clinical background found that, when contacting the patient by phone, if in doubt, she was able to conduct a capacity assessment and make a decision on eligibility based on that conversation.

“So, excluding the care home patients and doing the living at home, that was easy. The capacity one, I felt some of them were quite borderline capacity, some have some cognitive impairment and I felt they were probably ok” (GPA2)

“Absolutely, I mean there was one where it was clearly inappropriate, but there were others, like they did have, like there was a couple that said cognitive impairment but they had no diagnosis and when I spoke to them they fully understood what I was saying, they were able to reflect and demonstrated capacity regarding that phone call. So, I was more than happy to include them” (GPA2)

Another administrator, who was also the practice information technology specialist, set up electronic searches on the clinical record, which applied eligibility criteria, and suggested this was something that could be used in a definitive trial. All administrators indicated that they enjoyed this aspect of the trial as it was interesting and different from their normal role.

“Yeah, I’m so used to making searches that I automatically go into building searches rather than manually, everything is done that way...so if you can get access to the clinical system you can get the searches already made up and then you can just sent it to them to run them”

Overall, trial participants were content with methods used to invite them to participate, with a letter being the most acceptable method of contact. There was reluctance to respond to a phone call or email as first point of contact, as both these methods could be scams and participants tended to ignore them. Three out of the six trial participants had call screening on their telephones and said they would not answer unless they knew the person calling. It was suggested that an approach through a trusted source, such as a general practitioner, might be an alternative and effective method of inviting participation.

“I read through it and I thought yeah, why not? You don’t lose anything by doing this and I was interested, again, because of my original background” (P3)

“I think, not calling them, I think people get bothered too much by phone, I’ve got a... a call guardian on my phone and that stops people bothering me if I wish not to be bothered. Through the doctor might work quite well because people have faith in their doctor and anything coming from him or her might be a good way, but I didn’t mind being approached by letter” (P3)

No, I don't think I would respond to an email, I don't think so, I have so many, I only bother with the things I am really interested in or involved with, the rest of it goes to trash I'm afraid (laughs) (P3)

One important issue identified here was that five out of the six trial participants had difficulty recalling aspects of the trial including receiving study information and invitation letters. This had the potential to induce recall bias which may, in turn, lead to inaccurate results and was not anticipated in designing this aspect of the study. If this became apparent at interview, participants were provided with copies of the invitation letter and participant information sheet again as a stimulus to memory and this enabled some participants to comment and give feedback.

"Can I stop you there because I don't think I had anything from my doctor before, I think when you came and introduced yourself, I can't think, I must have been expecting you, but I didn't think it was anything to do with my doctor" (P4)

"Did I respond to that? (Asks wife about invitation letter). The nurse comes to take my blood pressure. It's nice to think that so much is going on" (P2)

7.5.1.3 Sub-theme: Randomisation

Randomisation at cluster level was conducted by the Clinical Trials Unit. Once consented into the trial, the participants were informed, by letter, of their allocation to the intervention or control arm. Trial participants understood why randomisation was required and did not mind which group they were allocated to. It was also noted that carers of the intervention participants reported that they were glad their loved-ones had received the intervention.

"Well, that's the way it was, that's the way it was, em, that's what I agreed to so, yes I had no problem with that" (P1)

"I didn't mind, I just took it for granted that I was in this control group, that was it, I think having been a medical secretary I used to see these sorts of things happening all the time and I've never thought about whether I would want to be in one group or another, just accept where you are, without argument (laughs)" (P3)

“Yes, and that’s what, I don’t know why, but I expected to be in that strand, I did and when I was getting these conversations, I thought, well, I think I’m in the other one” (P4)

“I think it’s nicer to be part of the study and to be the one the nurse comes to then you feel more involved than not” (C1)

7.5.1.4 Sub-theme: Collection of Outcome Measures

Outcome measures data were collected at baseline, three months and six months post-randomisation. These data came from three sources: (1) Clinical data from the general practice record entered by administrators onto the trial database; (2) Outcome measures questionnaires completed with trial participants by research nurses; (3) Data relating to completion of the intervention by community matrons. Administrators did not find it burdensome to return the information particularly as this was completed via a paperless database, something general practices are familiar with using. They appreciated the email reminders to complete the data submission and the direct link to the database was considered to be time-saving and convenient.

“It wasn’t too onerous, I did think will I be sitting for days looking at this, but it wasn’t that, em, so no, it was quite interesting to be involved and yes, it was good” (GPA1)

“Well it was nice to see that it was mainly paperless which is obviously something that as general practices we are going that way, so I liked the fact that you sent links and we could add the patient data onto that, em and also the fact that it didn’t take much time, it was easy to do” (GPA3)

Outcome measures questionnaires employed in the trial were extensive and took approximately one hour to complete. There were concerns that this would be an unacceptable burden for trial participants who may suffer high levels of fatigue due to frailty. On the whole, the questionnaires were well received with only one trial participant commenting that the questionnaires were long and repetitive, but she was still quite happy to complete them. All other trial participants stated that they did not

find the process of completion tiring, the questions were relevant and that they could complete them truthfully.

“I found it perfectly easy and I enjoyed the company actually, very easy, not at all stressful and quite relaxing” (P5)

“No, not at all, bearing in mind I had agreed to do this, so you do what is asked of you, it’s no good agreeing to something and then saying oh and getting bolshie over it” (P1)

“The questions they asked were all sensible to which I think I answered all of them as much as I could...I found them easy, I could fill them in genuinely, what I felt, what I did” (P1)

“In fact I was quite impressed, em, you get the idea that, you know, your information is going to be taken notice of” (P2)

An aspect of the study that was highly valued and enjoyed was the visits from the research nurses to administer the questionnaires. Trial participants enjoyed the social interaction these visits afforded, including the company of the nurses. The research nurses put trial participants at their ease, took time to carefully explain the purpose of the questions and made it an interesting and pleasant experience.

“They were helpful with me, they were helpful with what they were doing, they took the time to explain a few things that I asked, so that was good. I think they’ve been thorough, em, where I had a little problem filling in they helped or changed things, oh they didn’t change things, they spoke about it em and they were nice girls, I must say they were super to come in and talk and that’s it” (P1)

“In fact there is no question that the nurse was, I don’t know, I suppose it’s their job, em, to make it interesting, and, em, and strange as it may seem the actual questions and the way it was all done, to me was very professional” (P2)

“I’ve really enjoyed it, I don’t get the chance to speak to people much since I’ve not been able to go out over the past four years, so being able to talk to people and to find they wanted to talk about me was really quite enjoyable, no trouble at all...I had a whale of a time with one of them, yes, she said to me before she left “You’re a dynamic woman”. I said “what me?” oh, she really did me good (laughs)” (P4)

There was, however, some concern expressed that some of the questions did seem impersonal and ambiguous.

“I just filled in forms and answered questions and ticked boxes really, that’s what the whole process has been like, answer questions, tick boxes and sign, em, in that way I suppose it’s been quite impersonal” (P5)

“Some of them were... I didn’t know quite how to answer, and even the person asking the questions was like she didn’t know quite why that question was there, I can’t think of any examples at the moment but I felt with some of the questions they were a bit ambiguous, you could give two meanings” (P3)

Belief in contributing to public interest is reported to be an important motivation for older people in contributing to research (Baczynska *et al.*, 2017) and this is confirmed by this trial cohort. Trial participants appreciated a positive focus on the needs of older people and, while they understood that the research could confer no direct benefit to them, they expressed personal benefits and that the time commitment was worthwhile. Whether in the control or intervention group, trial participants and carers confirmed that they had learnt something useful in relation to their health and enjoyed the experience. It was reassuring to see that far from being burdensome, the experience was, generally, a positive one.

“I think we were just looking at it helping people in the future rather than helping (trial participant’s name) because it really hasn’t done anything to help him, so really we are just looking to the future for people that need help” (C1)

“I think the major thing is, I thought it was going to do something that was good for all, that was the main thing and that’s what they put over, that you are trying to learn about people like me and everybody else but put it all together” (P5)

“I am pleased that I might be in any small way offering some help, em, I suppose I should be pleased, I am pleased that in any small way I might be offering some help” (P2)

“No I didn’t think it would gain me any awards or any merit at all (laughs), it’s just being helpful to someone else” (P3)

7.5.1.5 Sub-theme: Clarity of study aims and purpose

One of the major challenges identified by trial participants and community matrons was lack of clarity about the aims of the study. Trial participants did not understand fully the purpose of the study despite being provided with the PIS and a verbal explanation at consent.

"I didn't really understand the purpose of the em, em, the study...it was just this not quite understanding the whole purpose of it...but it's just the fact that I didn't quite understand the reason for it, or the outcome of it, or the possible outcome of it" (P5)

"I think the only thing that would help or for me that I would like is if you were explaining what you were aiming at, what the final aim was, em, because we didn't really get that, I don't think the nurses knew so much, they gave a lot of information but where's it going is a different question" (P1)

Only one trial participant had understood and could articulate the study aims fully.

"I think the idea of the study was to find out how people who are living with some sort of disability or frailty are managing and what was stressed was, it's not just enough to be trying to get good results for people's health but also for their happiness, and I go along with that very strongly" (P5)

Community matrons also remarked that the participants did not always understand the purpose of the trial and expressed difficulty themselves in articulating the study aims, at least initially.

"And the patient didn't really understand what the HAPPI study was about, I found it quite hard to explain it actually. I think I've got better as time has gone on, but initially I think I felt nervous, I was trying to explain what the study was, they didn't really seem to understand themselves" (CM4)

"It was just when you said to them "I'm here because of the HAPPI" and they remembered it, but they couldn't always remember what it was for, and trying to explain the purpose of the study I found a little bit hard to start with and I think I was trying to use the words, a more academic approach which is not my natural, but I found it difficult to explain to them the purpose of the trial"(CM1)

"I think that the patients obviously get so much information that they don't obviously retain it or understand it and so that first visit felt like the blind leading the blind a little bit, I don't mean that rudely, but then on subsequent visits and with other patients, that's improved" (CM4)

The lack of clarity appeared to be related to the concept of feasibility, and it proved difficult to explain to participants that the study did not aim to prove effect of the intervention but tested procedures relating to the trial and intervention. This was compounded by the fact that the intervention was not prescribed or standardised, but

completely person-centred and, therefore, different for each person. This meant that neither the research team nor the community matrons were able to tell the patients what they were likely to experience apart from the basics of a nurse visiting them at home, potential number of visits and other broad details.

“I felt a bit clumsy on the first couple and then after that I thought what is HAPPI, what do I understand by it, then I tried to explain to them just like you said, we are looking at it in a different way, you know, in healthcare we are quite reactive, you know, but we are trying to be proactive, we are trying to know from your point of view what would help, we are trying to guide how you could be, I tried to unpick it a little” (CM1)

“And I think it was even harder because it was feasibility” (CM4)

“I think people can’t understand that, I think you are right, if it’s a or b they understand that, but I think, em, I don’t want to use the word woolly in a rude way, but I think it’s a bit more fluid then, that’s nice and woolly (laughs), it’s a bit more fluid, I don’t think people can always understand that, because I think you’re right, they hear a study and they think a or b, they don’t think it’s going to be an intervention that is kind of led by them and I don’t think they could get it really” (CM4)

The non-standardised nature of the intervention made it more difficult to manage patient expectations related to the study and what to expect after the intervention ended. It was suggested that an agreed script could be used initially to explain the aim and what could be expected, however, the community matrons did acknowledge that their ability to articulate the purpose did improve over time as they became more practised in this approach.

“I said we are just trying to see, can we actually do this, can we engage people, do they stick the course, do they stick with the six visits, do they feel they have contributed and that we haven’t wasted their time” (CM2)

“I would have liked a bit of a script that I could use on the introductions to all of them so they all started in the same vein and just for them to be a bit clearer, cos I struggled with the fact that they don’t, they don’t seem to understand it or know what it’s about” (CM4)

“I did feel like I did need something like a statement that was reflective of the research but was in everyday language” (CM1)

In discussing why the trial participants did not seem to be able to grasp the aim, one of the community matrons observed that these were “well” patients, often with busy lives and the study was not high priority for them. In addition, there was often a number of weeks between participant consent and first intervention visit, which led to participants having difficulty recalling conversations and written information about the study purpose.

“Yes, yes, and these patients are living a life aren’t they, that lady had been cruising and doing all those other things, so they will have forgotten, or it won’t be high on her list of priorities” (CM4)

“And I think a lot of people, I don’t mean to be rude, but they weren’t really readers, they sort of scan it, and the other thing they said was the duration, the time from when they were consented to actually having a knock on the door was actually quite a long time, and although they remembered HAPPI they didn’t really kind of know why I was there” (CM4)

7.5.1.6 Sub-theme: The HAPPI Intervention

The HAPPI intervention was designed to be entirely person-centred and its individualisation and unique content for each participant were key principles of the trial. Community matrons were provided with an assessment and care planning toolkit containing evidence-based tools constructed from the components of the intervention developed in the first phase of the study. As part of the evaluation, community matrons were asked to comment on the usefulness of the assessment pack/process and its relevance in clinical practice and all found it a useful resource which was comprehensive and supported a holistic assessment.

“But the assessment pack is definitely invaluable, I’m sure if the service, or whatever happens next evolves then it will evolve but fundamentally, it’s brilliant” (CM1)

“I think it (assessment and care planning toolkit) was absolutely brilliant and having that now is giving us permission, its updating what we already do, but having it in paper form and being able to refer to it is lovely, I want to keep it (Laughs), I want to make photocopies” (CM5)

"I thought it was very holistic as it was meant to be, I think it made us, or me feel I do an holistic assessment on my patients, and I think we do things holistically and don't realise we are doing it...so it kind of reaffirmed our role in being experts in holistic assessment I think" (CM3)

The whole suite of tools was never used in entirety with any trial participant, but rather the most appropriate resource was selected to explore or objectively assess issues in more detail and to help participants to understand their condition more fully. All community matrons found the conversation guide to be the most helpful and frequently used tool as it prompted discussions and guided the content of the ongoing intervention and care planning process.

"I think the conversation guide was the first one that we used and then you were about to dip in and out of the other tools" (CM2)

"Every first visit I used the conversation guide. On the first few visits I just used it as a guide, as a verbal prompt and a visual prompt, so actually, just completing that conversational guide you can find out so much, if you just do an holistic assessment with no, em, medical model, it is the conversational guide isn't it?" (CM1)

Some tools were found to be useful in guiding practice when the community matron felt they needed to add to existing skills and knowledge, in particular the assessment of depression, anxiety and loneliness.

"Then I did dip into some of the assessments. I did use HADS (Hospital Anxiety and Depression Scale) and the loneliness one quite a lot because that was hugely important, and that led to discussions about total symptom management, you know about how mood affects health, health affects mood, that kind of thing" (CM1)

"We did all the basic things like activities of daily living, and we did MUST (Malnutrition Universal Screening Tool) scores, and we did medication reviews at every visit. We looked at capacity a few times before you are convinced that they are ok, and we used MFRAT (Multifactorial Falls Risk Assessment Tool), you know, I used quite a few of the things, I tried the loneliness one" (CM2)

When asked if there were any missing components of the assessment process or tools, community matrons highlighted the need for a mapping of local voluntary and community support services, information on state benefits and some additional health assessment tools including a food chart, safeguarding flowchart and a particular

cognitive assessment (the Six-item Cognitive Impairment Test) which was in common use in the area. Paper copies of the tools and a toolkit folder were preferred over digital versions. A new clinical computer system had recently been introduced and there were concerns that the use of digital tools would be more time-consuming at this point in time.

The HAPPI intervention was designed to be completed in a maximum of six visits to the patient and the number could be tailored according to patient need. Community matrons agreed that six visits was the absolute maximum required, with the majority of patients requiring less. Having a limit to number of visits was perceived to be useful in that it enabled clarity, in terms of trial participants' expectations, and avoided fostering dependence on the community matron service. Contact details were shared with participants and they were encouraged to contact community matrons beyond completion of the intervention should problems arise or their condition deteriorated.

"I think six is good because once I realised I didn't have to do six, I got into a better 'right we've done this, we've done that we are gonna do this', fine, I don't think I would have needed more than six" (CM1)

"So I think more than six visits would not be good, to have that limit is good" (CM1)

"It was enough, it was enough, I don't think... I started introducing the PCP (Personalised Care Plan) at about visit three or four and then going back so that we could clarify things as they started looking at things in more depth so, I wouldn't think that you needed more than six to be honest" (CM2)

"I was hoping to wind him up today and not do visit 5 but no, he wants me to go back again in a fortnight, so yes, you've got to be careful about not fostering the dependency" (CM2)

These observations on toolkit content and number of visits will help to refine the design and inform the content of the intervention toolkit for a definitive trial.

7.5.1.7 Sub-theme: Training and Development

Community matrons described benefits for them, personally and professionally, arising from working as part of the study team, despite the demands of completing the study

tasks alongside managing their busy patient caseloads. Perceived benefits included having the opportunity to provide high-quality, evidence-based nursing care whilst updating on research methods and implementation.

“Well, I thought it was quite interesting, doing something that was slightly different, eh, contributing to the knowledge base really which is how nursing has evolved” (CM2)

“I think you’ve just got to look at what you were getting out of it and I just feel that I have had a bit of revision with the research process and it has been useful, it has reminded me about different aspects so that’s good” (CM2)

“So it was lovely to be able to go in and have that time, it was quality nursing, like old school nursing” (CM1)

In preparation for their role in the study, community matrons were required to attend a two hour face-to-face training session provided by the CI and to complete the online NIHR Good Clinical Practice (GCP) training package. The community matrons enjoyed the face-to-face training and reported that it was relevant and supported their role in the study. They appreciated the training pack provided, which reinforced the session, seeing this as a good resource and reminder once they were back in clinical practice.

“I liked the training session because it was face to face and you had the opportunity to interact and ask questions, what I really loved about the training was that it came with two files so the assessment pack came with me to every single visit and I loved having that” (CM1)

“Yes, that was fine, it gave us a good brief on what we would be doing, having the pack you could familiarise yourself with some of the tools if there was anything new in there, most of it we had come across before anyway” (CM2)

“I found that really good, I was quite excited by the pack, I know that sounds really sad, there were definitely tools in there, where I thought “oh this is really useful”” (CM3)

The intervention itself contained familiar components and so, in the main, community matrons were comfortable to deliver it supported by the assessment pack, although one community matron observed that it was helpful to have some additional support and mentorship.

“No, well we all learn in different ways, I learn when I am doing something on the job, but I did appreciate having someone who had done it before just to make sure I am taking in everything” (CM3)

“But I made sure that I was able to touch base with (names a community matron) and say “am I doing this right and do I photocopy this?”, so it was good to have somebody that was a little bit ahead of me” (CM3)

The online GCP training was less well received. Community matrons had difficulty accessing the site and found the training time-consuming and not entirely relevant to their role in the study. However, the training was recognised as necessary for all staff involved in trials and a useful opportunity for professional development that supported revalidation requirements.

“The training was long (laughs), long and I don’t think I could remember all of it. Yes and it makes you think “gosh this is very thorough” but I can’t really...oh I remember bits and pieces of it, but it’s a lot to remember.” (CM3)

“The online training was horrible (laughs) horrific and took a lot longer than I anticipated. But I think maybe it took me about five hours in total which, and I’m not sure I remember much of it if I’m honest, so your training and the pack brilliant, the online not brilliant” (CM4)

“We did the online training, the research training, which was quite in-depth, took quite a time...accessing that online e-learning, because it was an external provider, you know, it took a little bit of working out ... but you give a big hooray when you get your certificate and you put it towards your re-validation (laughs)” (CM2)

Whilst they were enthusiastic about working more proactively with patients earlier in the frailty trajectory, the community matrons acknowledged that this was a different way of working from their normal practice. This felt uncomfortable for them, at least initially, and they commented that they were not entirely equipped to work in this way.

“I wonder though, if I carried on seeing HAPPI patients for the next six months say, I wonder if my dialogue would develop better, do you know what I mean and whether I would be able to elicit, because in the past I’ve done courses on motivational stuff. I certainly enjoyed it more as it went on and I became much more confident, and I left those silences like I would in real life when I know my subject, and I’d give them homework which they all were a bit... but, so I wonder if I did it for another six months I’d be better at pulling a goal” (CM1)

“The first patient I felt like, I came away feeling a little bit upset like “oh my gosh I’m not doing this right” because it wasn’t terribly, it didn’t work out very well if I’m honest and I think some of that was learning about how to tackle this. I felt a little bit like I was

seeing them too early, so they felt they didn't need or didn't want to engage with what I offered and I suppose, I don't know, I'm not really used to people saying "No I don't need that" or "No I don't want that" so personally, I think the first patient really knocked my confidence and I really struggled" (CM4)

In addition, as part of the study procedures, community matrons were asked not to find out any past medical history or other information about the participants before the first visit. This was meant to ensure the assessment and care planning process flowed from the initial conversation without any pre-conceived ideas from the clinician. This request was a change for them as in their day-to-day practice, they would receive information from the referrer and gain past medical history, and medication lists from the general practitioner prior to seeing the person. Therefore, this change created unfamiliar territory for the community matrons and, whilst some reported that this was challenging, others enjoyed the opportunity to get to know the person without any prescribed agenda from their perspective. As the study progressed, all became more practiced and comfortable with this approach.

"Frightening, I found it frightening which is why I think my first one was all just a bit, because I felt a bit unsure...I'm going in blind without any information about the patient as well, which is alien to us, so I kind of went in very blind and the patient didn't really understand what the HAPPI study was about, I found it quite hard to explain it actually. I think I've got better as time has gone on, but initially I think I felt nervous" (CM4)

"I found it quite challenging because I am always leading the conversation and directing the conversation to get what I want because I want specific things so, em, it took longer, you know, so it was interesting (laughs)"(CM3)

"So, each first visit I knew nothing, I made sure that I was completely blind, obviously I knew their names and where they were, but that was it and that was brilliant and I really felt that I was able to get to know them a little bit before we went straight into what are the challenges etc., etc., em and the assessment forms, the guides" (CM5)

7.5.2 Theme Two: Filling the gaps in primary care

This theme presents views of trial participants and community matrons on the added value of the intervention and its potential to fill the gaps experienced by older people

in UK primary care. It is divided into two sub-themes and contains a participant case study, which indicated that, combined with delivery by skilled clinicians, this intervention may have wide ranging and multi-faceted impact.

7.5.2.1 Sub-theme: Meeting the needs of older people and carers

Trial participants gave compelling and often emotive accounts of their experiences of primary care services and were accepting of poor service and dismissive attitudes of clinicians. They recounted difficulty in obtaining appointments with general practitioners and lack of time allocated to them to discuss their multiple health issues.

“Well, I feel that it’s been very helpful, there has been times when, it has been very good because certain aspects of the way (CM4) handled things were very good because they were aspects that I was concerned about in general about the way the doctors work, em, and she sort of filled in the gaps, it was very good” (P5)

“No, it’s like you go into the doctors and you’ve got two or three little niggles, one major one and you don’t know as a layman, what could be related to what you know. In fact, I had that situation and I was asked, whether it was a humorous comment at the time, but it was commented “what is this buy one get one free day?” which didn’t, when you are not feeling well and you are not sure of that particular person, I wasn’t sure whether they were joking or not, it’s very detrimental” (P5).

“Yeah (CM1) was very helpful and was prepared to talk to me if I had a bit of a “what do you think is happening here?” and she said, she told me, you know, she was very good, very good, so I don’t mind her coming back (laughs). Cos I personally think the whole, all of the doctors and nurses thing is falling apart and we just don’t get looked after, especially as you get older, so it’s nice to have somebody come in and talk to you, it’s good” (P1)

“It’s difficult to make appointments to see your doctor unless you make them on the day and I always feel that if you make them on the day then it should be something urgent, but we find if you make an appointment and you can’t get one for about three weeks, when the three weeks are up you can be in quite a different situation” (P4)

Community matrons also alluded to these issues and acknowledged that it has almost become the norm for clinicians to convey their hectic workloads to the patient at every consultation as a justification for keeping the consultation short.

“Yeah, and I think they wait for a crisis now patients I think, oh you are very busy, oh the doctor is very busy and I almost feel embarrassed now that we keep saying that, I think we need to stop saying that because when patients are reciting it back to you, I think you are saying it too much” (CM1)

“Yes, you hear it and it’s not ok, if you want a lazy job you don’t work in healthcare, you are busy, but you don’t say it to the patients, the patients should not be able to pick up on that, they need to be able to feel that they have our attention when we are with them and I think we are losing that” (CM1)

“I think the patients really appreciated the time we took, I think that was said repeatedly, you know, so grateful for the time and they have never been able to speak to someone for such a long time and tell them about everything and they felt they were being listened to which in think is quite important” (CM3)

Trial participants highly valued the visits from community matrons and saw them as knowledgeable clinicians whose specific role was to discuss the challenges of their multiple health problems and who had time to listen to them. They described how the community matrons were interested in the detail of their health and social care issues, how they actively problem-solved and sign-posted them to sources of support. This was seen as providing what was currently missing in their interactions with primary care clinicians, particularly general practitioners.

“Oh yes, particularly if like me you are on your own and you’ve got some silly little niggle and if you can talk it over with someone, even if only for a couple of minutes, “oh, ok that’s fine, I can forget that, I can just go along with it”, whereas if no one talks to you about it, it’s still rattling round in your head and you don’t know whether it’s something that is important or of no problem at all” (P5)

“It was very useful, em, in general, that is what is missing in GP care generally, while I say they do as much as they can, because of the pressure they are under, em, you’ve got the feeling of being listened to with (CM2), quite frankly although my doctor is very, very good, she is rushed the same as every other doctor is, so I found that, the fact that (CM2) was actually listening to me was something I miss in general, I felt, I found that very, very good, yes” (P1)

Only two carers were interviewed, thus, there was limited feedback on the intervention from their perspectives. One carer did state that she would have preferred a more private assessment as she did not always feel she could be honest about her concerns and personal health issues with her partner present.

“Yeah, I think asking you as a carer in front of the person wasn’t good cos I didn’t answer honestly and you are not going to say a stress level of ten when it is sometimes” (C1)

More in-depth information regarding views of study processes could potentially have been gathered from additional interviewees, however, there were no negative comments relating to this aspect and both carers believed their loved-ones had gained benefit from the intervention and being part of the trial.

“Nothing bad, I think it’s done (P4) some good, but, you know I can’t put my finger on anything but I mean, she has looked forward to you people coming so she must have been thinking she is getting something good out of it” (C2)

7.5.2.2 Sub-theme: Reversing or managing frailty

Community matrons are advanced practitioners who provide care and support to the most unwell, complex, community-dwelling, multi-morbid patients. Such patients usually present to them when referred in crisis. The HAPPI study was viewed by the community matrons as an exciting opportunity to try a more proactive model of working in partnership with older people at an earlier stage of frailty progression, when there is a higher probability of avoiding or delaying adverse effects. They recognised that trial participants seemed far less unwell than their usual caseload and were enthusiastic about the opportunity to intervene earlier. They viewed trial participants as their potential usual patients in years to come and saw the intervention as a chance to delay that progression or prevent adverse outcomes such as loss of independence.

“But we now have people who are on practice nurses lists, we’ve got a lady having a hip replacement and having surgery, we’ve done falls work, I mean there is stuff that will prevent them hurling our way. I mean there is stuff we’ve genuinely done as well as the more holistic, difficult to quantify stuff, you know there are patients that have had interventions, that I decreased medications, postural drops picked up, real stuff” (CM1)

“I think that is advantageous and when I spoke to them about we are trying to be proactive rather than reactive and trying to look at where you are now and keep you well, make sure you understand your conditions and what to look out for and see that you can manage your own health, I think they got that and it was useful” (CM1)

“Because I feel that these patients are essentially my patients in ten years’ time, they are almost like an early version of our patients, so that’s why I think because we are used to working at a certain level, sometimes it was quite hard because I think we, I don’t want to use the word task, but we often are unpicking things, looking for problems and sorting them or addressing them and stuff and actually there wasn’t the level of difficulties that there are with our patients. So, I chose to do it that way to try and educate them, so I didn’t, I didn’t take control of things maybe like I do with my CM patients” (CM4)

There were occasions when the community matrons diagnosed serious health concerns in trial participants which, if treatment had been delayed, would have led to crisis. There was a strong belief that these patients may have slipped through the net of usual services as they were not yet sick enough or had not yet experienced a health crisis to bring them to a clinician’s attention, yet still required significant support to self-manage and preserve independence.

“Like one of the ladies we have ended up having to fast track into hospital for investigation, she had been waiting six weeks, she hadn’t contacted the GP, she’d been losing weight for six weeks and was waiting for me to go in and I said “have you made an appointment to see your GP?” “oh no” and she did it then and there and went to see him that day, it was really good” (CM5)

“They would have been, they would have presented with a crisis because they weren’t being monitored, yeah, and that’s important, that’s two patients that are now being reviewed annually that weren’t before” (CM1)

Community matrons highlighted challenges in articulating frailty in their discussions with trial participants and remarked on the correlation between physical and mental health and well-being in the study population.

“From my perspective as a nurse, I understand about frailty and I am passionate about it like many people, I think I’ve been talking about it even before it became, but using different words like performance status, functional ability and I’ve been talking about resilience to patients and speed to recover and all those things, I think you can see the value of this piece of work and I think if you are going to talk about frailty” (CM1)

“I mean she had become housebound from her anxiety, she had disengaged from her anxiety, she had disengaged from medicine, medical support, just from primary care, so if that festered and carried on she would have aged before her years wouldn’t she, I think and she could have had quite significant mental health issues if it’s not addressed” (CM1)

“And it was just really obvious that if we can sort out her pain and sort out her long term depression and anxiety that we can then look at social prescribing” (CM4)

A key finding in their intervention assessment, which was reported by all community matrons, was the high prevalence of loneliness and its impact on frailty progression. Community matrons noted that the existence of loneliness was present in the majority of trial participants and were aware of its significant link to mental and physical health issues. However, they felt ill-equipped to address this issue. While it was important to identify loneliness, it was hard to talk about, and they had little to offer in addressing the problem.

“The loneliness was phenomenally apparent, I was quite shocked... but these patients were capable of leaving the house and yet they had an overwhelming loneliness and one patient actually said to me “You are asking me all these questions but all it is is that I’m lonely” and I just felt that was a bit of a goose bump moment for me. I think that the patients that we see are perhaps more lonely than I have credited, but I have accredited it to a different word like isolation, and I think people actually can get out, they are able to talk, they have got the breath and yet they are lonely and the effect of that, and how they could even pinpoint themselves how this affects their mood and their ability to look after themselves and it was, you know, and it was hard to talk about, because saying to someone, yes I understand that you are isolated if you are unwell, or you are dying and people find it difficult to visit you, I can talk about that until the cows come home, but someone saying they are lonely, that’s a very personal thing, very emotional” (CM1)

“The loneliness one was interesting, its only three questions but it is a theme which crops up all the time with the type of patients we see, loneliness” (CM2)

“A lot of loneliness actually, because our CM patients, due to their complexities they often have people coming in like health care providers or care packages, carers, so they do have a certain turnover of people because they are often quite dependent, whereas, these are somewhere in between, so they are not still working, they maybe aren’t quite well enough to be collecting the grandchildren, that kind of thing, in terms of this particular person, but they are not at the point where they need care packages so actually she was in a really lonely bracket” (CM4)

“It really is and also you didn’t want to patronise and also if you take a conversation further, I have an expectation on myself as a practitioner that I will make a suggestion, but actually what is available for the management of loneliness is quite minimal” (CM1)

They noted a lack of awareness of community and voluntary sector support to address social isolation and the challenges of supporting trial participants to engage with these services, highlighting transport issues in a rural area as a major prohibitive factor. Some general practices had recently appointed a Social Prescriber and community matrons anticipated that these roles would provide better knowledge of and access to support services for this population.

“Because I did speak about socialisation and trying to get out, there is some stuff, but there is only one thing in this area where I can guarantee transport, two other things that provide some transport are fully booked and are at Eden and people are apprehensive about the hills and it also, I don’t mean this disrespectfully, but Cornish people see miles in a long way so even Eden seems a long way to them” (CM1)

“Yes, I mean I have referred to them PCDPs (Primary Care Dementia Practitioners), I have referred to Social Prescriber and Volunteer Cornwall and that’s what’s required, that social support” (CM5)

7.5.2.3 Case Study

It was not part of the original design of the qualitative study to capture participants’ stories, however, the opportunity to illustrate the potential impact of the intervention on participants manifested as part of the interview process with community matrons who wanted to tell their patient’s stories. Analysed using narrative enquiry, the following case study demonstrates the impact the intervention had on a trial participant as told through the lens of the clinician who delivered the intervention. Both the trial participant and the community matron have been given pseudonyms to preserve their anonymity.

Ruth, the trial participant is a white female in her early-seventies who lives with her husband, David, in a large village. David described himself as Ruth’s carer. Ruth was classified as moderately frail according to eFI and had not left her house for over a year due to anxiety and depression. Ruth withdrew from the HAPPI research study follow-up visits shortly after consenting, but opted to continue with the intervention.

Anna, the community matron told Ruth's story as part of her study interview as she believed implementing the HAPPI intervention had a profound effect on Ruth's health and well-being. Anna first met Ruth when she visited her at home to begin the HAPPI intervention. At the initial visit, Anna was very concerned about Ruth's level of mental distress along with multiple physical health issues.

"She was just so distressed, and it wasn't just like a discreet tear, she was sobbing, she had become very isolated, she didn't want to go out, she didn't want to talk to people, physically she hadn't been reviewed, her medications hadn't been reviewed, she was in low mood clearly, she wasn't sleeping, she had pain in her foot, there were lots of physical issues but her emotional health or well-being seemed to prevent her going out of the house and engaging in addressing any of that" (Anna)

In addition, Ruth told Anna about her worries regarding her estranged daughter who was subject to domestic violence. Anna also noted the emotional impact this was having on David and his feelings of helplessness in witnessing Anna's distress.

"...and there was some really distressing family dynamics which she couldn't seem to get through... she has a situation with her daughter who was in an abusive relationship and they had broken contact which was her ultimate distress" (Anna)

"It was always a joint visit with her husband and he was always very supportive, but he also seemed a little bit adrift as to where to go with the tears" (Anna)

Anna listened and allowed Ruth to tell her story, conscious that she needed to develop and maintain a trusting relationship. Over several consultations and using tools from the HAPPI assessment pack, Anna began to try to unravel the root causes for Ruth's distress and social isolation.

"So, I listened and I just agreed, got her to agree to let me back that was all I could achieve that visit. And, I went back, I took all the HAPPI stuff with me, I went back and we talked again, all tears, throughout the whole visit. " (Anna)

Ruth and David talked through their concerns and, despite Ruth's low mood and levels of anxiety, in partnership with Anna, they agreed manageable goals and a plan of care

to achieve them. Initially the clinician needed to take the lead due to the level of Ruth's distress and managing the distress was agreed as the first priority.

"I did a medication review, we started her on her medication, she definitely felt better even within two weeks, but definitely come six weeks that medication was helpful and she didn't want to stop it, and bearing in mind that she seemed to have an aversion to medication she actually must have felt something. But also her husband was a really good co-therapist, so he was able to see a difference in her, so that was good. And we talked about expectations and that it wasn't going to turn the key for her, that is was just going to give her hopefully the ability to move a little bit forward herself with some non-pharmacological actions" (Anna)

Anna talked about how, despite her low mood, it was important for Ruth to take control and manage her condition with her support.

"So then, once she had settled a little bit, we worked on some goals, but the thing is, she came up with the things she wanted to do...and interestingly of all the people I saw she was in the most desperate distress, and yet she actually moved herself quite a long way with just some gentle, gently cathartic interventions because I didn't do it all for her, I didn't wrap her up" (Anna)

Ruth was able, with support and honest conversation, to recognise how some of her behaviours were adding to her distress and make some plans to leave the house and engage in some activity.

"Then we looked at setting some goals about how she was going to manage her health better, but also I spoke to her quite honestly about that I was concerned that she was so housebound when she was physically completely self-caring... and so, I said to her about how the housebound aspect worried me and she took all that on board and so she started having, she goes to the supermarket the same time every week, so now they meet a friend there every week and they have a meal, so socialisation, and she could understand the value of that and they never miss it now and she even plans what she is having on the menu, she really looks forward to it, so that's cool isn't it?"(Anna)

In order to continue this progress towards a more active and less isolated lifestyle, Anna looked to next assess Ruth's physical health. Anna identified that Ruth had several long-term conditions, which were not being regularly monitored as she felt unable to leave the house and attend the general practice for her regular appointments.

Whilst Anna could have carried out the reviews as part of her visits in the home, she felt it was important for Ruth to regain responsibility for managing her conditions.

“I kept saying to her, you need to be proactive about your health, you need to manage your own health, so you need to book your blood tests, you need to keep on top of things, if you know they are needing doing, don’t be cross that the surgery haven’t sent you a letter, phone them up and tell them you need them doing, it’s your health, take control” (Anna)

In order to support Ruth, Anna facilitated the process by taking steps to ensure Anna would attend an appointment and that the general practitioner was aware of some of her concerns.

“I know it sounds a little bit extreme, but then, I had to turn the key somehow, so I found out who her favourite GP was, I went and spoke to them, I gave them a handover of the level of distress, I got her an appointment at a time of the day that she felt able to attend it” (Anna)

Ruth had some blood tests while she was at the surgery and the results were within acceptable limits which provided some reassurance. Having facilitated a successful encounter with a clinician, Anna next addressed Ruth’s foot pain by referring her to a podiatrist who Ruth also saw at the general practice. This resulted in resolution of the pain and so enabled her to consider more activity outside of the house. Following discussions about the links between mental and physical health and maintaining well-being, Anna reflected to Ruth that during their conversations, she could be distracted from her distressing thoughts and so asked her to consider if there was an activity that she would consider to provide distraction and promote well-being. Anna and David had previously enjoyed walking and were enthusiastic about trying to build short walks into their daily routine.

“She says that she ruminates, she constantly ruminates but even when she was at her most tearful, by the end of an hour I could get her laughing, so she does respond to that type of distraction. So we talked about that and so they now go for a walk three times a week together as husband and wife from the house, and when I went to the last couple of visits especially the last one, it’s just so lovely because she was able to see that she feels better for going out, she was able to say that” (Anna)

Anna described how she felt out of her depth in hearing Ruth's concerns about her daughter's situation and how she lacked training in supporting relatives of those who experience domestic violence. She was not prepared to leave this issue unaddressed and so, with Ruth's permission, reached out to other clinicians within the multidisciplinary team for support.

"Well, how do you help someone with that, I can't say that's not distressing can I? But, I also felt a little bit out of my depth on that, so platitudes were not cool, so I spoke to the CPN (Community Psychiatric Nurse) in MDT with her permission just to ask for some advice, as to how do you support a family of people that are going through domestic violence, because I don't know" (Anna)

The CPN provided information on sources of support for Ruth and Anna shared this with her. Ruth was grateful for the information but did not want to access support at that time. Interestingly, on the final HAPPI intervention visit, Anna raised the issue again to ensure that Ruth was still aware of the support and could access it if needed. Anna admitted she felt scared to do this as she feared opening old wounds and causing more distress, however, it became clear that having someone listen to her worries and provide sources of support had enabled Ruth to change her thinking and reduce her level of anxiety about the issue.

"I was a little bit nervous about bringing up the domestic abuse again because I didn't feel skilled, do you know what I mean? That is a massive subject isn't it? And she said to me and I said, "how do you feel about your children?" thinking "oh gosh, I'm going to make her cry" but she actually said to me "I can't change it but I definitely feel like I can get help if I need to" which was a massive step. I don't know how that key was turned and I don't know whether it's just because we saw that she was distressed and didn't leave her distressed and actually just stuck with it a little bit" (Anna)

When telling Ruth's story, Anna commented on the stoicism of frail patients and linked this to Ruth's age group who do not want to be a burden or ask for help from a doctor

unless they perceive their situation to be very serious. She also reflected that Ruth and David were aware that things were going wrong but did not know who to ask for help.

“...especially that generation where a GP is a GP, I think that unless they need a doctor they don’t know where to go and it snowballs doesn’t it, but I don’t think people know who to call and I think that we have distilled unwittingly this culture of you know “don’t come to A&E unless, don’t come to Minor Injuries unless, we are really busy, there’s no appointments, I’m sorry but the doctor can’t call you back”, we cultivate this “we’re busy” and I think that generation they don’t want to be a burden, they don’t want to bother us, their leg’s not falling off” (Anna)

“I believe that she needed help, she knew she needed help, but she didn’t know how and I kind of feel that it was a fortuitous letter, that somehow, they needed something but didn’t know where to go kind of thing” (Anna)

Anna strongly believed that had the study and the offer of the HAPPI intervention not come along at that point, Ruth would have deteriorated further and suffered significant mental and physical health decline. She was excited by the opportunity to intervene at an earlier stage when it was possible to make significant changes to prevent further deterioration and ultimately a health crisis.

“I mean she had become housebound from her anxiety, she had disengaged with her anxiety, and she had disengaged from medicine medical support, from primary care, so if that festered and carried on she would have aged before her years wouldn’t she? I think and she could have had quite significant mental health issues if it’s not addressed” (Anna)

“I just do think the HAPPI study, it’s almost, it is exciting, but it’s almost a bit of sweet excitement because I just think if we could do a little bit more at this moderate stage, you know catching them before they enter into this downward spiral it would just be phenomenal” (Anna)

Anna was keen to emphasise that, while Ruth had been able to re-gain control of her health and take responsibility for it in the future, this was through her support and she made sure that Ruth had a safety net if things deteriorated. This included reinforcing the need to continue her re-engagement with primary care and giving permission for her to make contact if needed.

“I said to them, you know, just keep my number and if you feel like things are just getting difficult you should be phoning the GP and making an appointment, and if you phone me I’ll be getting you to the GP surgery, but if you feel like you are slipping backwards then just call me, don’t get that distressed” (Anna)

Anna reported that in just six consultations, there were significant changes to Ruth’s mental and physical health and well-being and this had impacted positively on both her own, and her husband’s happiness.

“So it did take a little bit of work but that lady now has had a complete review, a complete medication review, she has had medication changes that have made a difference, she’s had not only pain management, but pain resolved, she’s now physically exercising three times a week, she’s socialising with a meal once a week and she can do a whole visit with a community matron and not cry! (laughs). It’s amazing. And her husband was just so grateful, massive, you could see. And the last visit was just full of laughter... I was so happy on that last visit, I was like “Wow!” There were hugs and kisses galore.” (Anna)

In conclusion, this case study has demonstrated the positive impact of a holistic assessment and care planning intervention for a frail, older person with complex physical and mental health needs. Using the HAPPI intervention framework and toolkit, the community matron was able to attend to and make sense of the person’s health needs and plan care accordingly. However, whilst the framework and toolkit provided structure, the high level of skill and knowledge demonstrated by the community matron cannot be underestimated. Anna, as an experienced nurse qualified to a high level, showed enhanced clinical assessment, facilitation and counselling skills enveloped in outstanding compassion and empathy. In addition, Anna was able to recognise limitations in her skills and seek support from other team members, providing holistic management to her patient. This enabled Ruth and her husband to move from a position of extreme distress and powerlessness to re-engaging with social support, health services and re-gaining enjoyment in their lives. This was achieved through partnership working with the community matron who provided that support to self-care

and independence. Delivery of the HAPPI intervention provided the opportunity to be proactive in addressing problems which would have led to crisis in the future. Whilst it would appear that the intervention could be used successfully within a definitive trial where all participants are unlikely to need such intensive support, adequate clinician training to ensure appropriate skills level will be essential.

7.5.3 Theme Three: “I’m a person not a patient”:

A key objective of this study was to determine whether the HAPPI approach can support moderately or severely frail older people to play an active role in making decisions about their health and social care and in the prevention and management of their long-term conditions. This theme reports on the successes and barriers to this approach from the perspective of the community matrons and trial participants. There two sub-themes.

7.5.3.1 Sub-theme: *Setting health goals*

Trial participants did not recognise their role in shared decision making and goal setting; instead they looked to the clinicians to lead this process. Irrespective of their level of frailty, trial participants did not view themselves as patients in need of care and support from a nurse. A home visit by a nurse was viewed as indicating a much more serious health need than their own and because their condition/s were stable they did not recognise the need to be proactive in preventing deterioration and crisis in the future

“See, I hadn’t really understood (CM2)’s role, I hadn’t realised she was going to be a nurse who would actually come and visit, because I still don’t treat myself or think of myself as a patient, you know...so, the thought of a nurse coming round to see me when I haven’t asked for a nurse, I don’t feel, I’ve never had a home visit before, it just hadn’t occurred to me that that was what her role was going to be” (P5)

“I’ve never thought about a nurse coming round and seeing you in your home, if I want medical treatment, I call up the doctor and lo and behold a month later he comes and gives me a home visit you know?” (P5)

Community matrons remarked on the passivity of participants in managing their conditions and expectations that clinicians will lead decision-making in relation to health goals. Community matrons acknowledged, however, that they were used to directing the consultation when patients are very unwell and in need of crisis support. Trial participants appeared less sick but still displayed passivity in the person-clinician relationship, expecting the community matron to have the answers and set the goals.

“And then you look at goal setting, well that fascinated me because I love personalised care planning, I always have, advanced ceilings, I love all that, but these people could not formulate a goal but they wanted to me to, and that shocked me because after all that spiel about what should happen and I would say “What do you want to get out of this, what would you like to set as a goal?” and drawing a goal out of them was incredibly difficult” (CM1)

“I think when you reflect that back and say “what do you think you could do?” there is almost a frown of puzzlement because there isn’t that expectation that they have to do anything, they’ve come to me for the answer... I thought that would be a bit different because I was anticipating that they would be slightly younger and more mobile, I mean mobile in a really functional way, that they might have been a little more proactive and have more of an opinion, but no. I found that quite fascinating, the goals as really difficult, really difficult. If I suggested something they were really happy, excuse the pun (laughs) but they did seem to want that paternalism that I was trying to avoid, if that makes sense?” (CM1)

“I mean, in terms of goal setting I can’t think of one that wanted to set goals... and it was motivation, it is motivation to set a goal and is the goal relevant to them at the time, and I think for a lot of patients in this instance it’s not just a possibility. And they have already set their own goals and their goals are not our goals it’s their goals” (CM5)

“So more or less all of them have now got a PCP (Personalised Care Plan), I’ve left them with PCPs so they have short profiles in, so they are quite astounded by that because they have never seen all that before, but they find it very interesting and very reassuring that all these things are being dealt with and documented... I think the goal setting is the hardest bit isn’t it, in that patients are not used to that, in when we are doing preventative work” (CM2)

Working in partnership to set personal health goals proved to be the most challenging aspect of the intervention. Trial participants did not appear to be motivated or acknowledge they had a role to play in making changes to their health and well-being. This was underpinned by lack of knowledge about their health conditions and impacted

by family and relationship dynamics, which fed into the need to remain passive in relation to their health and care.

“I think as usual, you never cease to be amazed at about how little they understand about their own conditions , do they really, they can be very vague.” (CM2)

“The people that we see have had this condition for at least a decade or more and I’ve always been quite surprised how inert they are in the management of their long term condition, and sometimes that’s because they’ve never been told or never been shown, I doubt that’s completely the case, I think that’s human nature when you are working and you are told you have a bit of hypertension or a bit of COPD you don’t correlate that with 10 or 15 years’ time, I think that’s just human, but I think they expected me to fix it” (CM1)

“There were lots of physical issues but her emotional health or well-being seemed to prevent her going out of the house and engaging in addressing any of that, and there was some really distressing family dynamics which she couldn’t seem to get through” (CM1)

“So one of her goals was actually to have some time to herself and yet at the moment that is an impossible goal because the effect it has on him (partner) then impacts on her, and then so trying to set that goal he felt he was being marginalised, you know and that wasn’t good for him. And so there are a lot of dynamics” (CM5)

Community matrons addressed these challenges with a range of strategies to encourage more active participation and partnership and this proved successful in improving participants’ health and well-being. These included changes of terminology to be more person-friendly, providing praise and encouragement for all goal-setting attempts, however small, signposting to sources of support rather than actively providing the support needed and ensuring goals were small, achievable and measurable, so that progress was apparent.

“I did wonder if it was my phraseology and if it was new terminology to them, so I did use phrases like “What do you think this can do for you” “What can we do together”? I did try to soften it. I did wonder if they had anticipated that I wouldn’t have anything to answer” (CM1)

“The importance of personalised care plans, the importance of communication with patients because even though they knew their conditions, they, I think personalised care planning was another step that maybe they had forgotten about or just needed reminding of why they were doing what for their particular condition, sort of reinforcement.... Yes, I think I felt more at ease to actually give them a bit more responsibility and encourage that responsibility for their own health...yes you are doing

the right thing and actually you could take it a bit further, take it a little more forward, maybe go and see the GP about that problem, almost giving them permission” (CM3).

“They were a bit alienated with that, but from the first visit, we just set objectives for the next one. So, for the first visit, I just let them talk, they spent the whole hour talking about themselves and their perceptions and then that was when I was able to say, we are able to make some measurements which will give us baselines, so that when I come back next time, what I want to do is ...” (CM2)

“So it’s just about encouraging them and saying this is about your own self-care and self-management and “well done” type of thing. That’s me, that’s the way I’ve always worked. It isn’t about “give it to me to do”, it’s about “you can do this, you are going to be absolutely fine”, you know and in my view that’s the role” (CM2)

“I became very focussed on what they understood about their health, what they thought their health needed, what they thought would help and I enjoyed finding out what they knew and what they did to help” (CM1)

Community matrons’ strategies appeared to be successful in most cases and trial participants and carers were able to describe how the community matron had worked in partnership with them. This included making health and care improvements such as developing a plan of care and support, which persisted beyond the life of the intervention. They particularly appreciated the focus on contingency planning, developing a health information plan to share in an emergency and having the opportunity to discuss and agree a treatment escalation plan.

“Very helpful, she introduced things that we, my husband and I didn’t know about like the information that is collected and I can keep here so that if anything happens to me, paramedics or whoever can come in and refer to that straight away. I think that’s an excellent idea” (P4)

“Fine, she was very easy to talk to, I got the feeling that she knew what she was talking about and was very knowledgeable in all areas of the subject and I was happy to listen to her advice and take it, as far as that went, yes” (P4)

“We talked about bladder control and that was useful, I’m sure there were other things that I can’t recollect just like that. She told us about, at the end we heard about is it called NICE? Where if my husband were taken ill he puts something in his telephone a number so if he were taken ill say if he were out shopping and he was rushed off in an ambulance they could find out that there is somebody at home who it totally dependent on him and expecting him back” (P4)

C1: “I think the bit they are doing at the end, filling in information sheets for him to keep here, in case there is nobody here, I think that is a brilliant idea”

Interviewer: So you mean the care plan that they leave, that is done with you and is left in the house?

C1: Yes, I think that's a really good idea because if I'm not in and something happens and they come, he's got that sheet and we only have to find somewhere to keep it where they will find it" (C1)

"Yes planning early is a good thing because then the NHS should understand the patient more than when they go there and they don't know them from Adam" (C1)

7.5.3.2 Sub-theme: Implementing new models of care and support

Community matrons articulated the tension they felt in trying to fully commit to the proactive HAPPI approach alongside their normal role and how this may have impacted on their ability to be more thorough in supporting goal-setting and shared decision making. They described how their own caseload of patients in acute need would always take priority as they were deemed to be more in need of immediate attention. Consequently, work with trial participants was sometimes delayed. Community matrons were disciplined with time-management but still needed to be flexible to meet the needs of participants and their own patients.

"Ok, its more work than I thought it would be and if I'm honest I have found that quite tough because I work part time. My community matron caseload is quite taxing so I have found it challenging" (CM4)

"I didn't realise how much the community matron role has changed and this is, I keep saying, it's like going back to how it used to be, which isn't a bad thing, it's just that our ability to see and get to know patients like this has diminished" (CM5)

Community matrons who worked part time, or who were participating in the study outside of their normal geographical area faced additional challenges of making time for study work and lack of usual support networks. Furthermore, at the time of the study, the NHS Trust was implementing a new digital clinical records systems and this, alongside the paper recording for HAPPI, was challenging for some. Generally, completing study activity was difficult in the time scales even with small numbers of participants for each community matron.

"The only thing was I would, I put my own work before the HAPPI because we were into escalation and some of my patients were quite poorly, the RIO project has come up which has taken quite a lot of my time so it's unfortunate, so there is one chap that I've still got and I should have seen, so it's kind of delayed, I had two visits booked up which were put off because kind of things went a bit awry in my own job" (CM3).

"But that was part of the challenge because I've only got one day a week, I've managed to swap around so when one patient was poorly and I saw them on the Friday, I did not want to wait to the next Friday so I saw them on the Tuesday and just swapped days around" (CM5)

"I would feel a little bit stressed if we got a bigger study and we had to do this as well because then I would feel I would be letting you down because I hadn't done it in the appropriate time frame" (CM3)

Community matrons discussed whether it would be easier to manage if there were designated nurses for the study, who only saw HAPPI participants. This may have enabled more focus on the study and less feelings of being spread too thinly across the HAPPI study and their usual caseloads. Other suggestions included that aspects of the intervention could be delivered by others, particularly the parts relating to social isolation and loneliness, which may be better addressed by voluntary and local community groups. However, there was a general acknowledgement that these services are not widely available.

"I would have enjoyed it more and found it, if I was the HAPPI Chick...as opposed to a HAPPI Juggler (laughs). You can use that as a quote!" (CM4)

"No, I don't think in terms of those, if we talk about clinical goals a lot of those clinical goals would be my goals not theirs and the goals they wanted to achieve then yes, I can facilitate them to a degree, but they don't need a community matron to do that, but they need some support, yeah definitely and that is lacking and there isn't that support" (CM5).

To summarise this theme, the challenges of goal-setting, shared decision making and promoting self-care were strongly articulated by community matrons. In addition, taking responsibility for their own health did not feature as a strong concept in interviews with trial participants. This may be because they did not view themselves as unwell and,

therefore, despite having multiple long term conditions and significant frailty, did not see themselves as having a role in its management. This demonstrated the inherent complexity of living a life with frailty and multiple health needs and how, even with these challenges, the HAPPI intervention may impact positively on health and well-being.

7.6 Qualitative results summary

Themes identified in the qualitative component of this trial present challenges and opportunities that may be critical to the success of a future definitive trial. They include factors relating to trial procedures and implementation of the intervention itself. In the following discussion chapter, this information will be used in combination with data from the quantitative component to enable a more comprehensive and multi-layered understanding to inform the definitive trial design.

Chapter 8: Feasibility randomised controlled discussion

8.1 Chapter introduction

The fRCT with its embedded qualitative study aimed to determine the feasibility of delivering the novel HAPPI intervention in primary care to frail older people and to test potential trial methods to inform the design of a definitive RCT. Its objectives were related to the feasibility of trial processes and the intervention and evaluation of outcome measures. In this chapter, recommendations for the design of a definitive RCT are made based on discussion of the findings. As a mixed-methods study, the principles of complementarity have been adopted using the quantitative and qualitative study findings to ensure all objectives were met including whether it is feasible to conduct a RCT and to understand participants and clinicians experiences of participating in the trial (Plano Clark & Ivankova, 2016). Results have been interpreted to demonstrate where the aim and objectives have been achieved, and discussed in relation to the existing evidence base.

8.2 Trial Processes

This fRCT has identified important factors related to processes including evaluation of participant identification using the electronic frailty index (eFI); determining achievable recruitment and follow-up rates; evaluation of the sites' willingness to identify and recruit eligible patients; and the willingness of patients to be recruited. These factors will be discussed next in sections 8.2.1 to 8.2.8 and will inform future work related to the design of a definitive trial.

8.2.1 Site recruitment and retention

Evaluation of the ability to recruit and retain general practices as sites within the RCT was an important feasibility parameter. Previous research has found that recruiting and

retaining general practices in clinical trials is challenging (Wilson *et al.*, 2000; Yallop *et al.*, 2006). Bower *et al.* (2014) identified a lack of evidence about factors associated with the recruitment of general practices to research studies, thus, it was important to understand how to maximise engagement or overcome any barriers. Some authors have noted that interest in the research topic, invitation method, and general interest in research are important in recruiting general practices into studies (Dormandy *et al.*, 2008). These aspects were demonstrated as important in engaging general practices in this study. General practice contracts were amended in 2017 to include the mandatory identification of severely frail patients (NHS England, 2017). Consequently, many of the general practices were interested in frailty but had little knowledge about effective management strategies. Participation in the study gave them an opportunity to learn more about the topic, use a systematic tool to identify their frail patients and to test a new clinical management model.

Initial access to general practices proved difficult. The CI initially wrote to all general practices, explaining their anticipated roles in the study, commitment required and funding provided, with no response. Primary Care Research Network (PC-CRN) nurses then identified 13 research-active general practices and two who had not yet participated in research, but were keen to be involved. It was useful to identify the research-active practices and to be able to approach them through a known and trusted source i.e. PC-CRN nurses. However, the two research-naïve practices who participated proved to be efficient and enthusiastic in their approach to screening and data collection and met the study milestones just as effectively as the more experienced practices. The CI conducted individual meetings with representatives of these general practices. There was a good response, with eight practices meeting eligibility criteria and six agreeing to participate as sites. Whilst it was encouraging that

site recruitment targets were met, it proved labour intensive with the CI committing to multiple meetings with the associated time and travel. This was accounted for in the study grant timeline and costings, however, when estimating funding for a full scale trial across disparate sites, other methods of communication should be considered, such as virtual meetings and the involvement of local research champions.

Once recruitment targets were met, it was important to consider retention of the general practice sites to avoid potential withdrawal of a cluster, which would have threatened integrity of the trial. Certain actions have been demonstrated to improve retention of general practices in clinical trials (Dormandy *et al.*, 2008). These include effective communication, easy data-collection methods, and payment upon meeting pre-agreed targets. All of these factors were implemented in this trial. The CI maintained regular contact with the practices by email and in person. Some of the practices did struggle to meet study milestones due to capacity and the CI provided support in the form of advice, information and practical help with tasks involved. With a small number of sites it was possible to provide reminders of time scales and physical presence in the surgeries when needed. However, in the definitive trial, with larger numbers of sites and participants, it may be more cost and time-effective to allocate funded hours to a research assistant to carry out some of the tasks relating to screening, enrolment and recruitment to ensure timescales are met.

As part of determining the study design, there was discussion about the easiest methods of general practice data collection. Most UK general practices have adopted a “paperless” approach in clinical record keeping and practice administration (National Information Board, 2015) and were familiar with electronic recording of clinical information. In this trial, data collection was designed to be paperless and achieved by uploading the information onto the trial database in response to timed e-mail

reminders. Finally, at the outset, sites were made aware that payment for research costs was available and all sites claimed the funding. In summary, there were important factors identified that facilitated full recruitment and retention of general practices as study sites. In the definitive study, consideration of these factors will need to be built into planning and funding.

8.2.2 Participant recruitment

If a clinical trial is unable to recruit and retain the target sample size then statistical strength, as well as internal and external validity cannot be guaranteed (Bower *et al.*, 2009; Tyson *et al.*, 2015). Slow recruitment may delay the completion of the trial, which can ultimately reduce the impact of findings on clinical practice (Kadam *et al.*, 2016). The recruitment and retention targets in this fRCT were achieved, however, there were challenges in various aspects of the recruitment process, and their resolution provided important learning for the definitive trial.

Rate of recruitment was significantly influenced by having capacity at the sites to complete the initial identification, invitation and screening procedures. At one site, support was provided by the CI who applied eligibility criteria and compiled a list of people to be invited to participate. This accelerated the process and demonstrated that, with targeted support, initial procedures could be completed within the specified time frame. There is evidence of under-recruitment of older people to research studies, particularly RCTs (Clegg *et al.*, 2015). Studies have reported high participant exclusion and refusal rates especially in trials recruiting older people with frailty (Azad, Molnar & Byszewski, 2008). These issues did not appear to affect recruitment to the HAPPI trial since, despite some delays, recruitment was completed as anticipated within ten months, however, the process was sporadic and did not follow the planned study timetable. In a definitive trial, with larger numbers of participants, it is likely that

significant support may need to be provided to sites to complete the recruitment processes. The support given by the CI and its influence on timely recruitment demonstrated the importance of dedicated research support capacity and this needs be adequately funded so should be built into a grant application for the definitive trial.

8.2.3 Identification of frail cohort

The trial sample of 414 frail patients was created by random sampling of the eFI patient list at each site. Each site had varying numbers of moderately and severely frail patients and, overall, there were less severely frail patients identified than was anticipated. Based on available evidence (Seymour, 2018), it was predicted that, for an average-sized general practice (14,000 practice population), the eFI would identify approximately 1000 moderately and 500 severely frail people. After random sampling and application of eligibility criteria, it was predicted that this would have resulted in the target of 60 participants. In fact 56 participants were recruited across the six sites (36 moderately and 19 severely frail).

The reason for the lack of severely frail patients is not clear but may be due to the following factors. Firstly, two of the sites had a smaller than average practice population and so did not generate the expected numbers of severely frail patients. Secondly, one of the largest sites had no care homes within their geographical area. There are a higher number of severely frail patients residing in care homes so this may have led to less availability of severely frail patients for recruitment, however, care home residents were later screened out through application of eligibility criteria. Finally, the eFI is a computerised algorithm that relies on effective clinical coding of symptoms, signs, diseases, disabilities and abnormal laboratory values to populate and give scores (Clegg *et al.*, 2016). Whilst all sites said their clinical coding was completed effectively,

coding practices are known to be variable with limitations to the coding systems in the UK (de Lusignan, 2005).

The number of severely frail patients then reduced further at later stages of the screening process when letters were sent inviting them to participate. Physical and cognitive limitations accompany severe frailty and this may have inhibited response to the letters and follow-up phone calls (Harris & Dyson, 2001). To the author's knowledge, with the exception of one pilot study (Lansbury *et al.*, 2017), this fRCT is one of the first studies to use the eFI as a research participant identification method. This method had advantages, since the use of an automated algorithm means that selection of potential participants is rapid and straightforward. Multiple frailty screening tools are available (Section 1.4.4) and many have been evaluated, but there is no consensus on a definitive screening method for use in research (Walston, Buta & Xue, 2018). Whilst its ease of administration was positive, there were some concerns expressed about the use of the eFI to identify frail people. Community matrons, for example, reported that their assessment of the severity of a participant's frailty did not always correlate with their eFI score. It is known that there may be a risk of over-identification of the frail population because counting the number of eFI-comprising deficits results in overestimation among those registered with the general practice for longer periods of time (Alharbi *et al.*, 2020). In addition, as previously mentioned, the algorithm requires effective coding (Reeves *et al.*, 2018).

NHS England has recommended that, following screening using eFI, a clinical assessment is conducted to confirm degree of frailty (NHS England, 2017). This may not be feasible in community-based clinical practice and there is a lack of evidence that clinician's judgement is more effective than screening tools to diagnose frailty. A recent study by van Walree *et al* (2020) found that sole reliance on clinical judgment

to identify frailty could result in missing patients with relevant impairment. In order to design a feasible method, a second step of self-completion of the PRISMA-7 questionnaire was added into this study to confirm the diagnosis of frailty. This did lead to the screening out of significant numbers of participants at that stage (34%), which may account for the false positives generated by the eFI. This does support the requirement to identify large numbers of frail people at the outset to provide an adequate sample size following eligibility screening.

To summarise, an accurate method of differentiating degree of frailty is essential because CGA-based interventions are most effective for those who are moderately and severely frail, rather than non-frail or mildly frail older people (Hoogendijk *et al.*, 2019). Evaluation of the eFI as a participant identification and screening tool in this feasibility study has provided valuable information for a definitive trial. The eFI is easy to administer and can rapidly screen for moderately and severely frail patients in a practice population (accepting the risk of false positives). However, it did not identify sufficient numbers of severely frail patients. The addition of PRISMA-7 reduced numbers further but was a necessary step to ensure more accurate diagnosis of frailty and, therefore, ascertain appropriateness of participants for the study. In order to make enrolment processes manageable for the sites, eFI patient lists were randomly sampled to produce 90 people to be invited to participate. For the definitive trial it is recommended that larger numbers of moderately and severely frail patients are sampled so that there is a larger “pool” of potential participants to be invited, or an alternative frailty identification method is used. This is discussed further in section 8.7.

8.2.4 Participant eligibility

As a feasibility trial, eligibility criteria were as broad as possible to facilitate full recruitment. In order to reduce workload for primary care clinicians, the trial evaluated

application of eligibility criteria by practice administrators who had no clinical background. Eligibility criteria were designed to be easy to check using the clinical record (aged 65 years and over, living at home, not known to the community matron service and having mental capacity to consent). Practice administrators reported that it was not onerous to find the information to complete eligibility checks and, in the main, completed the screening log fully. It would appear that a clinician is not needed to apply eligibility criteria as long as they are unambiguous and there are clear instructions to follow.

The eligibility criterion of possessing mental capacity to consent was not in the original research proposal and was added by the NHS Research Ethics Committee (REC). The original proposal recommended inclusion of those who lacked mental capacity where assent could be provided by a consultee. This was to ensure that large numbers of frail people with cognitive impairment were not excluded from the study. The application of this criterion reduced the numbers of potential participants further with 20 participants excluded at either at eligibility screening or at consent visit. In addition, mental capacity, or lack of, was often not formally recorded on the clinical record. Consequently, this was not identified until the consent visit. If in doubt, the research nurses, following training, conducted a mental capacity assessment as part of the visit.

The REC referred to approval criteria set out in Section 31 of the Mental Capacity Act that the research must be connected with an

“...impairing condition affecting the participant or its treatment and research of equal effectiveness could not be carried out if confined to participants with capacity”.

(Mental Capacity Act, 2005, p.25)

They concluded that, as a feasibility trial, these two criteria could not be met. It is likely that in a definitive trial, these criteria could be satisfied and it would be possible to

include those who lack mental capacity and have a consultee who is willing to give assent. This will ensure an important group of the population are not excluded from participation and is likely to enhance recruitment by providing adequate participant numbers for the definitive trial. If those who lack capacity to consent are included, it will be important to consider the additional support to enable participation. This may include acceptable and inclusive methods of inviting participation and the use of appropriate outcome measures instruments. These issues are discussed further in section 8.3.4.

8.2.5 Participant Enrolment

Methods of inviting eligible people to participate in the trial were assessed. Previous studies have demonstrated that the number needed to be screened to recruit one older person is approximately 3:1 (McMurdo *et al.*, 2011), and so maximising engagement was an important feasibility parameter. The plan was to screen 540 people for eligibility, which, it was estimated, would have led to 180 people to invite to participate. As previously discussed, only 414 people were available for screening, so it was imperative to maximise recruitment by using effective and appropriate enrolment methods. A recent review of studies recruiting older people found that recruitment methods using referral by recognised agencies reported higher rates of eligibility and enrolment (Ige *et al.*, 2019). However, there is mixed evidence in relation to enrolment through primary care. Some studies have demonstrated that approaching potential participants through primary care is an efficient method of gaining access to a large number of older people with the condition under study (Barnes *et al.*, 2005), nevertheless, it is important to be aware of over-restrictive gatekeeping by clinicians, who may exclude people for reasons other than specified eligibility criteria (Lee, 2005).

In this trial, enrolment procedures were designed to avoid clinical gatekeeping by using the automated eFI and then practice administrators to apply eligibility criteria and invite participation. Overall, trial participants were content with methods used to invite them to participate, with a letter from a trusted source named as the most acceptable method of contact. In summary, the learning for the definitive trial is that a letter from the general practice is the preferred approach and that the use of non-clinicians in administering and following up invitations to participate is feasible.

8.2.6 Clarity of study aims and purpose

Study aims and purpose were stated in the PIS (Appendix 11) and a verbal explanation was given at consent visit. Community matrons remarked that the participants did not always understand the purpose of the trial and expressed their own difficulty in articulating the study aims. It appeared that the aims of a feasibility trial were more difficult to articulate and for participants to understand. In addition, the non-prescriptive, personalised nature of the intervention meant that it was more difficult to explain exactly what participants would receive if they were randomised to the intervention arm of the study. In her paper on feasibility studies, Tickle-Degnen (2013) acknowledges this issue and highlights that this poses more challenges to researchers whose interventions are complex. In the HAPPI study, the intervention is individualised, made up of a number of blended components that act together to affect outcomes, which in themselves are not standardised. These features can make it difficult to meaningfully describe aims and the study “offer” to participants.

However, other factors may also be influential, such as regulatory requirements, which mean that PISs contain compulsory text that has little meaning to participants and consequently may be difficult to understand. The primary aim of the PIS should be to provide information to help the potential participant in making a decision as to whether

to take part in research or not (Innes *et al.*, 2018). A systematic review by Kirkby *et al* (2012) found little correlation between the regulatory items included in Health Research Authority guidance and the topics participants rate as important in informing their decision to take part in research or not. In fact, Armstrong *et al* (2012) suggest that PISs are written to comply with regulatory procedures as opposed to supporting potential participants' decision making. The PIS in this study was co-produced with PPI representatives, but these were research aware and, therefore, wording and content relating to the study purpose may not have been as easy to understand as it could have been for potential participants. In addition, as a novice CI working with research-naïve clinicians, it may be that the team lacked the skills to clearly verbalise this information to the patients.

These aspects will need to be carefully considered for the definitive trial, with more user-friendly information and the production of shorter, more meaningful “scripts” that can be used by the research team with participants to initially articulate and then reinforce study aims. During qualitative interviews, participants said they had not read the PIS fully and that it did not aid their understanding. One solution to this issue was suggested by the community matrons, who would have appreciated an aide-mémoire; a very short, written explanation of the study aims, which they could have used to explain the study to participants. This could also be incorporated into the PIS, invitation letters and used at consent visits to provide a consistent, coherent description at all stages of recruitment. An aide-mémoire will be developed in consultation with PPI representatives in preparation for use in the definitive trial.

8.2.7 Participant retention

McMurdo *et al* (2011) report dropout rates of between 5% and 37% in their review of studies that recruited older people. Certain strategies can improve retention in clinical

trials, such as the provision of monetary incentives and the use of short outcome measures and questionnaires (Brueton *et al.*, 2014). This study did not have the finances, or ethical approval, to provide incentives and the outcome measures questionnaires were lengthy and numerous due to the need to test feasibility of multiple outcome measures. An interesting finding from the qualitative study concerned participants' motivations for taking part. Trial participants appreciated a positive focus on the needs of older people and, while they understood that the research could confer no direct benefit to them, they enjoyed participating and felt that the time commitment was worthwhile irrespective of their allocation to the intervention or the control groups.

It was reassuring to see that, far from being burdensome, the experience of participating was, generally, a positive one. This is borne out by the literature where studies have found that clinicians judge older people as vulnerable and needing protection from research (McMurdo *et al.*, 2011), yet, older people themselves display as much or more willingness to participate as any other sector of the population (Peterson *et al.*, 2002). Therefore, the research team aimed to enhance the experience of participants. The research nurses were warm and friendly in their approach and all outcome measures were completed at one visit at each time point to reduce burden. This personal approach, whilst more time consuming than administering postal questionnaires, contributed to excellent retention rates and is recommended for adoption in the definitive trial.

8.2.8 Safety

The risks associated with taking part in this trial were assessed as low (Lyndon *et al.*, 2019) but assessment of safety was an important aspect of feasibility. Acute illness resulting in hospitalisation, new medical problems and deterioration of existing medical problems were to be expected in this population of moderately and severely frail

patients (Hoogendijk *et al.*, 2016a). It was anticipated that participants would experience frailty syndromes, such as admission to hospital for falls, immobility, delirium, incontinence and iatrogenic side effects of medication regardless of participation in the trial (Turner & Clegg, 2014). Therefore, the Trial Management Group recommended that only AEs and SAEs related to the trial would be reported by the research team and then screened by the CI for relatedness and expectedness according to the safety reporting flow chart (Appendix 18). There were no reports of AEs or SAEs during the intervention or follow-up period. This may have been because, although falls, hospital admissions and suchlike did occur, they were judged to be unrelated to the trial.

Whilst it is encouraging, it is unusual not to have any reported AEs and it is known that the collection, reporting and analysis of AE data in clinical trials are inconsistent (Phillips *et al.*, 2019). For a definitive trial, a clearer definition of what AEs should be reported and when is recommended. As an assessment and care planning intervention, it is unlikely that the majority of the HAPPI intervention components could cause an AE, however, some components such as medication review/de-prescribing may have the potential to lead to harm. For example, de-prescribing of a drug may cause an increase in symptoms or event such as a fall. It is recommended that AEs relevant to other de-prescribing studies (Potter *et al.*, 2016) are reported in the definitive trial. These include falls, fractures, GP consultations and admissions to hospital. Then the same relatedness and expectedness assessment is completed by PIs before reporting to the Trial Management Group and Trial Steering Committee/REC as appropriate.

8.3 Evaluation of outcome measures

A two-fold assessment of the feasibility of trial outcome measures was conducted; (1) to verify proposed outcome measurement and follow-up schedules and (2) to evaluate proposed outcome measures to determine a primary outcome measure or potential multiple outcome measures for a definitive trial. Evaluation included acceptability of outcome measures to participants, ease of administration and sensitivity to change at trial time points. To date, studies evaluating the care of older people with complex needs have sought to measure a variety of outcomes using a plethora of outcome measures. In their systematic review of chronic care programmes for older people, Drouin et al (2015) included 14 studies measuring a broad range of impacts. These included health and social care system utilisation, such as emergency department visits, hospitalisations and re-hospitalisations, hospital bed days, care home admission and numbers of prescribed medications; quality of care; and individual impacts such as health related quality of life and function. In relation to quality of life, at least six instruments were used and seven different instruments used to measure function. The review authors concluded that this lack of uniformity in outcome measures is a common issue in evaluation of interventions targeting older people and this limits comparison of results across studies. In addition, it can be difficult to ascertain whether negative study results are due to an ineffective intervention or insufficient/inappropriate measurement.

In order to alleviate these concerns, in 2018 a standard set of outcome measures for older persons was published (Akpan *et al.*, 2018), which established a minimum set of outcomes for evaluating healthcare for older people. The outcome measures in this fRCT were drawn from this document. Data from a combination of participant-reported outcome measures of physical and mental health (SF-36), confidence in own ability to manage health and in role as participants in care (LTC-6), loneliness and isolation

(UCLA-3), function (Barthel Index), health-related quality of life (EQ-5D-5L) and site-reported outcome measures (death; cause of death; number of hospital admissions and readmissions; total number of days spent in hospital; number of prescribed medications) were collected. The outcomes of health, self-efficacy, loneliness, function and quality of life are key features of the development of frailty and concepts often used by older people themselves to describe what frailty means to them (Britain Thinks, 2015). However, as a feasibility study, it was not known which outcomes could be impacted by the HAPPI intervention, so it was important to determine feasibility of a range of outcome measures to inform a definitive trial.

8.3.1 Ease of administration and completeness

Data for all outcome measures proved feasible to collect with high levels of completeness. All participant-reported outcome measures were collated into one questionnaire booklet (Appendix 15) and completed at one visit by the blinded assessor, consequently, there was very little difference in completeness rates between outcome measures. There are known disadvantages to face-to-face assessment in that it can lead to bias (Sackett, 1979) and a blinded assessor in a cluster trial has the potential to be unblinded if the participant reveals allocation during the interview (Bello, Moustgaard & Hróbjartsson, 2014). However, in research with older participants who may have physical or cognitive impairments, McMurdo et al (2011) advocate a more pragmatic approach enabling involvement by having a researcher to read the question to support those with visual or hearing impairment. This approach does not conform to accepted rules of standardised interviewing when administering questionnaires and it can be argued that interviewers' contributions may increase bias and influence responses (Schaeffer & Maynard, 2002). DeVries et al (2014) recommend a

collaborative approach where the interviewer can interact with the participant to ensure understanding and encourage positive interaction.

In conclusion, in assessing feasibility for a definitive trial, it appeared that completing outcome measures questionnaires in a face-to face visit enabled excellent completion rates and improved participants' experiences, which have enhanced retention. Such an approach needs to be balanced with a standardised administration of the questionnaires to reduce potential for bias. An information sheet for use by blinded assessors will be developed with standardised prompts and instructions on how the questions should be read and/or repeated to ensure consistency with all participants.

8.3.2 Timing of outcome measures

The study protocol stated that participant-reported outcome measures should be completed up to seven days before or after their due date (calculated from date of consent). In reality, it proved problematic to meet this target, with up to half of all visits completed outside of the protocol window (after the due date). Whilst the research team were diligent in booking visits within the window, often visits were cancelled by the participant. Reasons given for cancellation were either related to ill health, hospitalisation of the participant or other commitments such as health-related appointments. It appears that +/- seven days around the due date is an overly ambitious target and it is recommended that this is extended for the definitive trial. A range of seven days before and 14 days after the due date may be more achievable, but it should be recognised there may need to be flexibility in timing of outcome measures collection.

Outcome measures were assessed at three-months and six-months after consent in this fRCT. As a feasibility study, the purpose was not to assess efficacy of the intervention but to test if it was possible to collect the data. It may be that a longer

follow-up period is required in the definitive trial as, by their nature, interventions that address symptoms of frailty may take some time to show effect. There is no agreed follow-up period advocated in the literature. A recent systematic review of studies assessing single frailty interventions reported follow-up times of between three-months and one year (Kidd *et al.*, 2019). When evaluating complex interventions, it is recommended that follow-up should be as long-term as is possible, within the constraints of the trial, to determine whether short-term changes persist, and whether additional benefits or hazards may manifest at a later time (Craig *et al.*, 2008).

In the definitive study it will be important to assess change in outcome measures during the life of the intervention (three-months), following completion of the intervention, and to assess sustainability of any effect in the longer term. It is, therefore, recommended that follow-up time points for the definitive trial are at three-months, six-months and one year. This recommendation needs to be balanced with the potential disadvantages of longer follow-up, which may include increased adverse events and reduction in retention with more participants choosing to withdraw from the trial (Kearney *et al.*, 2018). However, in analysing results of five large RCTs, Akl *et al.* (2012) did not find significant associations between the extent of loss to follow-up and the scale of treatment effect, therefore, these factors may not be influential on the outcome of the definitive trial.

8.3.3 Sensitivity to change of outcome measures

Although the aim of this feasibility study was to test the procedures for the administration of outcome measures, it also enabled examination of their sensitivity to change in people with moderate and severe frailty. Responsiveness of the instrument to detect change refers to the ability to perceive improvement/deterioration, an important attribute for determining the efficacy of the intervention (Singh & Aithal,

2018). Analyses from this fRCT must be viewed with caution as the study was not adequately powered to detect change, so evidence was sought from the literature, which showed variable information on sensitivity to change in the outcome measures under study. The SF-36 and EQ-5D-5L (used with older people) appear to be similar in their ability to measure change over time with some evidence of greater sensitivity to lower levels of morbidity in the SF-36 (Brazier *et al.*, 1996). The UCLA-3 has been shown to be sensitive to small changes in loneliness over time (Velarde-Mayol, Fragua-Gil & García-de-Cecilia, 2016). There is no published evidence on sensitivity to change relating to the LTC-6 scale. Finally, an integrative review found no evidence related to the ability to detect change over time for the Barthel Index in older people (Liebzeit, King & Bratzke, 2018).

In this fRCT, all outcome measures appeared able to detect change over the time. In all domains of the SF-36, mean scores were low and ranges were wide, which may indicate the participants were heterogeneous in health status. It is of note that scores in physical function and general health domains decreased in the intervention and control groups over time. This change may be expected in participants who live with moderate and severe frailty and concurs with evidence that function deteriorates as frailty increases in severity (Chen *et al.*, 2018; Milte & Crotty, 2014). It may be that, in a definitive trial, a stabilisation of scores could be seen as positive rather than an expectation of improvement. This highlights the importance of the randomised control design in long-term conditions such as frailty, where natural progression is likely to be deterioration. The design allows comparison between intervention and control groups and can be used to detect any differences in health-related quality of life that may be related to the intervention.

As in the SF-36, data from the LTC-6 questionnaire revealed wide ranges of response and large standard deviations, with overall scores lower in the intervention than the control group. Mean scores rose in the intervention group at both study time points, whereas, in the control group they fell at 13 weeks but rose above baseline at 26 weeks. Data from the UCLA-3 remained stable across all trial time points in both groups and did not appear sensitive to change. This does not concur with the work of Velarde-Mayol et al (2016), who investigated the validity of this instrument. It may be that this tool is less likely to detect change over a relatively short period of time. In addition, it may be that the contact provided as part of the trial improved participants' self-perception of their loneliness. This is borne out in the qualitative data, which revealed that community matrons recognised how lonely many of the participants were, and by participants themselves, who reported how much they enjoyed the social interaction of the study visits. This provision of social contact could be mitigated by asking participants to complete postal or online questionnaires, but this needs to be balanced against the excellent completeness rates achieved by study visits. Other loneliness/social isolation tools could be considered for the definitive trial. In its evaluation of measurement of loneliness in adults, the Office for National Statistics recommended the use of the UCLA-3 combined with a single question "How often do you feel lonely?" as this enables capture of different features of loneliness and supports with more direct language (Office for National Statistics, 2018a).

Mean scores for the Barthel Index rose at 13 weeks and remained higher than baseline at 26 weeks in both groups. As the trial was not powered to detect change, this is likely to be coincidental and was not in alignment with SF-36 data on function and mobility. Whilst the Barthel Index is widely used in older people and rehabilitation trials, studies have found that its ability to detect change in highly functional individuals is limited,

with a ceiling effect (Quinn, Langhorne & Stott, 2011). This may be important to note for a definitive trial. Many of the moderately frail participants were highly functioning and so this may not be the most sensitive outcome measure. Data from the EQ-5D-5L index values appear to confirm these high levels of function. Across the five health domains, participants reported high scores for self-care, mobility, anxiety and depression and usual activity, indicating that they experienced little or no problems.

On analysing data from all participant-reported outcome measures, it may be that the control group were less functionally impaired than the intervention group. It is not known why this would be, due to random allocation of clusters to intervention or control, however, there may have been demographic differences in the practice populations. To inform a definitive trial, it may be necessary to closely examine the eFI and PRISMA-7 scores of the individual participants, to see if there is any difference in level of frailty severity within the clusters and, if so, adjust accordingly to ensure equivalent levels of frailty within intervention and control groups. In a definitive trial, with larger participant numbers, it would also seem appropriate to analyse data for the moderately and severely frail participants separately, which may lead to less heterogeneity of scores. This is recognised as a methodological limitation of the study and will be discussed further in Chapter Nine.

In assessing site-reported outcome measures, as previously discussed in relation to safety reporting, it is notable that there were no deaths over the time of the study. This was an unexpected finding. Studies investigating frailty as a predictor of death have found that frailty was an independent predictor of three-year mortality (Hao *et al.*, 2019; Yang *et al.*, 2018). However, there are important differences in these studies' populations and methods compared to the HAPPI fRCT. Hao *et al.*'s research was carried out on a population who had been admitted to hospital and Yang *et al.*'s work

was with older people in a nursing home setting, whereas the HAPPI study focussed on a community dwelling-population. In addition, both former studies examine three-year mortality rates, whereas follow-up in the HAPPI study was limited to six-months. A systematic review of the impact of frailty on mortality in community-dwelling older people reported that it was associated with poor survival with a dose-responsive reduction in survival related to increasing number of frailty criteria (Shamliyan *et al.*, 2013). Recruitment for the study was conducted predominantly in the spring and summer months when there may be less excess winter-related deaths (Hajat & Gasparini, 2016). If recruitment had been conducted over the winter period, it is possible that mortality may have been higher as those who are frail are more susceptible to winter illnesses, such as influenza, leading to hospital admissions and deaths. CGA-based interventions are known to have an effect on mortality in hospitalised patients (Stuck & Iliffe, 2011), however, it is less clear whether such an effect can be replicated in primary care, therefore, this will be an important outcome for the definitive trial. It may be necessary to have a longer follow-up period to ensure this effect is captured.

Data on numbers of admissions and readmissions and days spent in hospital were collected with low numbers in both allocation groups. Once more, as the trial was not powered to detect difference between groups, results should be treated with caution. Numbers of days spent in hospital were lower in the intervention group, but this was influenced by the small number of participants, and one participant in the control group who experienced an extended hospital stay. The final site-reported outcome measure concerned numbers of prescribed medications. Numbers were similar in the intervention and control groups at baseline. Interestingly, numbers of medications rose in the control group at 13 weeks and fell again to baseline at 26 weeks. However, in

the intervention group, fewer medications were prescribed at 13 weeks and with a further reduction again at 26 weeks. It is known from assessment of intervention tools used that medication review was one of the most frequently used tools. Review of medication is a key aspect of CGA as certain medications are known to have significant adverse effects in frail older people (Hilmer & Gnjidic, 2017). A randomised controlled trial showed that de-prescribing reduced the number of regular medicines consumed by frail older with no significant adverse effects on survival or other clinical outcomes (Potter *et al.*, 2016). It would appear that the community matrons in the HAPPI study, reviewed medication regularly as part of the intervention and consequently may have reduced numbers of medications prescribed. Therefore, numbers of prescribed medication would appear to be a clinically important outcome measure for a definitive trial.

8.3.4 Selection of a primary outcome measure

As stated in the Statistical Analysis Plan (Appendix 13), the choice of primary outcome measure/s for a definitive trial was guided by a number of factors: the number of outcome measures completed at the study time points; those most acceptable to participants; ease of administration in primary care; and those which are sensitive to change at the different time points. As discussed in the previous sections, all outcome measures appeared to broadly meet these criteria in that there was little missing data, they could be administered easily at one study visit and appeared able to detect change over time and difference between the allocated groups. HAPPI participants indicated that they did not find any of them burdensome to complete.

Whilst it is encouraging to see the outcome measures met feasibility criteria, an additional factor needs to be considered in selecting a primary outcome/s measure for a definitive trial. As previously discussed, people who lacked mental capacity to

consent were excluded from this trial on the instructions of the NHS REC (Appendix 19). It is recommended that the eligibility criteria for the definitive trial do not exclude those who lack mental capacity if they have a consultee who can provide assent and can complete outcome measures as the participant's proxy. Recent research has demonstrated the coexistence of physical and cognitive impairments and that cognitive frailty can enhance the impact of physical frailty leading to negative health outcomes (Majnarić *et al.*, 2020), so for this reason, it is important that the definitive trial is representative of the whole population group. In addition, in the HAPPI trial, none of the participants had communication difficulties that prevented participation in collection of outcome measures, but this does need to be considered.

Using participant-reported outcome measures assumes the person can understand the question and express a response. Proxy responses are a reasonable alternative when patients have cognitive and/or communication difficulties, which prevent them from answering outcome measures questions (Graham, 2016). There may, however, be the potential for measurement error or bias if there is disagreement between the proxy and participant responses (Neumann, Araki & Gutterman, 2000). The literature on each outcome measure has been reviewed to assess for effectiveness of completion by a proxy.

The SF-36 has shown only poor to moderate agreement between participant and proxy (Pierre *et al.*, 1998). The Barthel index has been shown to have wide limits of agreement between participant and proxy but it is, nevertheless, recommended for use as a proxy instrument (Chen *et al.*, 2007). There is no available evidence for the use of the LTC-6 as a proxy tool and it is recommended that the UCLA-3 is not administered using a proxy (Office for National Statistics, 2018a). The EQ-5D-5L is validated for

proxy completion and there is a proxy version for use where people are not capable of reporting on their health-related quality of life (EuroQuol, 2019).

An alternative may be to consider outcome measures that are designed for use by those with cognitive or communication difficulties. A review by Ready et al (2003) demonstrated that there are multiple scales designed to assess quality of life in people who live with dementia. These differ in their assessment methods and suit different research situations, for example if a carer is present, or the extent to which the participant can contribute. The authors caution that there is a lack of evidence as to which tool is superior in demonstrating change over time. Given this uncertainty, it may be appropriate to consult with relevant stakeholders to determine an inclusive primary outcome measure for a definitive trial. These stakeholders should include those with cognitive impairment, carers and relevant representative organisations such as Dementia UK.

To summarise this discussion of the selection of a primary outcome measure for a definitive trial, the advantages and disadvantages of each participant-reported outcome measures have been fully evaluated. It is recommended that the EQ-5D-5L instrument is adopted to measure health status and health related quality of life in a definitive trial. This tool was well completed, easy to administer and has the advantage of a proxy version, which can be used with consultees in a full trial. It is not known whether responsiveness to change is maintained when completed by a proxy and this does not yet appear to have been assessed in the literature. However, one study aims to assess responsiveness to change of the proxy-completed EQ-5D-5L in older patients with substantial multimorbidity and polypharmacy and results are expected in a future paper (Bhadhuri *et al.*, 2020). In addition, the EQ-5D-5L-VAS can be used for a future economic evaluation as a validated tool for calculating quality adjusted life

years (QALYS) (Whitehead & Ali, 2010). In addition to measuring health status and quality of life, the six dimensions of the EQ-5D-5L give a wider picture of functional status, independence, pain and mental health status. Use of this outcome measure will provide a broad assessment of the characteristics of frailty, which can be impacted on by a CGA-based intervention.

It is recommended that prior to commencement of a definitive trial, a project team of stakeholders including older people, carers and organisations representing conditions that affect cognition is formed to agree a primary outcome measure. It may be possible to include an outcome that is important to those with cognitive deficits, and the use of an appropriate outcome measure that is inclusive and meaningful to that population.

8.4 Estimation of sample size for a definitive trial

As a cluster RCT, participants were randomised at site (cluster) level, however, data were analysed at individual level and it is planned to adopt this method in a definitive trial. Over-estimation of effect size can occur as similarities between individuals in clusters can reduce variability of response compared to individual randomisation (Killip, Mahfoud & Pearce, 2004). It may be possible to increase the cluster size by recruiting more participants at each site, however, a high number of clusters and with a lower number of participants in each will result in the smallest design effect and so is statistically preferable. In terms of feasibility, this approach would also reduce burden on individual community matrons, with less participants per clinician. This fRCT has demonstrated that initial engagement of general practices can be challenging, therefore, in reality, and dependent on resources available, large numbers of clusters may not be recruited to a definitive trial. Therefore, it will be important to consider the design effect if similar numbers of clusters but with larger numbers of participants are recruited and statistical advice will be sought prior to commencement of the trial.

8.5 Refinement of the HAPPI Intervention

The HAPPI intervention was designed through an e-Delphi survey and research stakeholder consultation (Chapter Four). One objective of this fRCT with embedded qualitative study was to assess its acceptability to participants, carers and clinicians, further refine the intervention content and assess any barriers to its delivery.

8.5.1 Acceptability of the HAPPI intervention to participants

Studies of nurse-led assessment and care planning interventions in primary care (although not specifically including older people with frailty) have demonstrated high levels of acceptability to patients. A systematic review of studies of case management of patients with complex health needs by nurses in primary care (Stokes *et al.*, 2015) found the intervention had a significant effect in improvement in health status and quality of life. In this fRCT, it appeared that the person-centred assessment and care planning approach delivered through the HAPPI intervention led to high levels of satisfaction among participants.

Trial participants talked about how HAPPI filled gaps in their current primary health care service, by providing time, conversation and problem-solving with a skilled clinician. A recent study by Kelly *et al.* (2019) reported that older people display low levels of satisfaction with primary care services and express strongly-held perceptions that their health needs are overlooked (Kelly, Mrengqwa & Geffen, 2019). The researchers report that these perceptions relate to lack of prioritisation of older people, negative and unhelpful attitudes of healthcare staff and clinician shortages leading to rushed consultations. For older people who live with frailty, continuity of care is important to manage the complexity of their multiple health and social care needs (Saultz, 2003), yet experience of continuity of care is reportedly low (Gjevjon *et al.*, 2014). The results of these studies resonate strongly with findings of the HAPPI

qualitative study and it is encouraging to note that the HAPPI intervention appeared to provide many of the features of continuity of care that appear to be missing from mainstream primary care for frail older people. These include the allocation of a clinical care manager who acts as a conduit for information and communication and who has dedicated time to form a trusting relationship with service users and carers (MacInnes, Baldwin & Billings, 2020).

8.5.2 Feasibility of the HAPPI intervention to clinicians

Regular patient discharge in primary care services helps to manage capacity and can ensure that patients with the greatest need are able to access support in a timely way (Roland *et al.*, 2005). The trial allowed evaluation of whether it was possible to conduct a time-limited, CGA-based assessment in primary care where the lead clinician is a nurse rather than a doctor.

To support the movement of CGA from secondary to primary care, the BGS recently published a Comprehensive Geriatric Assessment Toolkit for Primary Care Practitioners (Turner *et al.*, 2019). This toolkit is 48 pages in length and takes a minimum of two hours to complete. The BGS themselves acknowledge that completion by general practitioners may not be possible due to short appointment times and lack of capacity in current UK primary care. Additionally, its full completion may not ensure a person-centred approach as not all components may be appropriate for all frail older people.

The HAPPI intervention toolkit promoted an alternative flexible, person-centred approach. The initial assessment was based on a two-page conversation guide and one-page CGA summary, which community matrons reported as being quick and easy to complete. These guided the development of the personalised care and support plan and the use of the additional standardised assessment tools if they were appropriate

for that person and their assessed needs. The clinicians found this approach to be feasible in terms of time to complete, with the pack of additional assessment tools used for support if they did not have specific knowledge regarding a certain health condition.

The community matrons welcomed the opportunity to test a more proactive model of working with frail people earlier in their frailty trajectory. They perceived that there was more opportunity to make improvement or prevent further deterioration before a crisis occurred. There is systematic review evidence to support early intervention by proactive management of mild to moderate frailty (Puts *et al.*, 2017; Travers *et al.*, 2019) and the community matrons strongly believed this could be an effective approach in their clinical practice.

In particular, the community matrons highlighted the negative effects of social isolation and recognised this as a risk factor for frailty development in the participants. Loneliness has shown to be detrimental to health in multiple studies. A meta-analysis in 2015 concluded that social isolation resulted in a fifty percent increase in premature death and is an equivalent risk factor for early death to smoking and a sedentary lifestyle (Holt-Lunstad *et al.*, 2015). There were limited resources available to address this issue in local communities in the study, however, the new role of social prescriber had been implemented recently at some of the sites, and was highlighted as a potential solution. Social prescribing is a way of linking patients in primary care with sources of support within the community to help improve their health and well-being, usually through a link worker (Bickerdike *et al.*, 2017). The community matrons were hopeful that these new workers could signpost the participants to groups and other community resources that could address their loneliness and social isolation. As loneliness is an independent risk factor for frailty and given its high prevalence, it would be important

for the definitive trial to ensure that similar resources are available and able to be accessed by the clinicians delivering the intervention.

8.5.3 Refinement of the HAPPI intervention content

One of the aims of the study was to further refine and finalise the content of the HAPPI intervention. The intervention pack contained two documents that were to be used with each participant (the conversation guide, and personalised care and support plan) and an additional suite of 29 assessment tools to be used selectively based on the participants' assessed needs and health conditions. All assessment tools were used during the course of the trial, but not with all participants. The most frequently used tool was the medication review summary and this was often used repeatedly over several visits. This may suggest that review of medication was an important component that needed to be considered with the majority of participants. As previously discussed, suboptimal prescribing and polypharmacy can lead to poor health outcomes for frail older people such as adverse drug reactions, hospital admissions and subsequent healthcare costs (Lund *et al.*, 2010; Passarelli, Jacob-Filho & Figueras, 2005), so regular review is important. Other frequently used tools were those relating to assessment of severity of frailty, pain, functional independence and caregiver strain. Although the HAPPI intervention was aimed at participants, an assessment tool for caregiver strain was included advocated by the PPI consultants and as increased caregiver burden is known to be associated with the physical frailty of the care recipient (Ringer *et al.*, 2017).

A recent realist review of most effective approach to CGA in care homes noted that engagement of a multidisciplinary team (MDT) was required (Chadborn *et al.*, 2019). In the HAPPI fRCT, referrals to and the involvement of other health and social care services were evaluated and there were few referrals made to other services across

all participants. It is not clear why the number of referrals was so small. It may be that there was little need to involve other services, or that referral was not wanted by the participants. Integrated care by a MDT is an effective way to improve outcomes for people living with complex long-term conditions, however few multidisciplinary programmes have been specifically designed to manage frailty (Hendry *et al.*, 2018). Further research is required to evaluate the specific added value of integrated care for frailty, but for the definitive trial it seems that MDTs would need to be available for the lead clinician to involve or refer to as required according to the needs of participants.

In summary, the ethos of the HAPPI intervention is that it is a unique package entirely based on the needs of the individual participant. However, given the frequency of their usage of certain assessment tools in this fRCT and the likely outcome measures for the definitive trial, it may be appropriate to standardise the assessment package to include mandatory assessment of severity of frailty, medication, pain, function/independence and carer strain with the remaining assessments used as appropriate and as time allows. Research has been evolving whilst the HAPPI trial has been conducted. A recent meta-analysis recommended that resistance exercise coupled with optimising nutrition improved physical performance in frail older people (Macdonald *et al.*, 2020). Based on this new evidence, the intervention for the definitive trial should include assessment of ability to participate in resistance exercise (as part of the mandatory functional assessment) and mandatory assessment of nutritional status.

8.6 Barriers to implementation of the HAPPI intervention

In their paper on the Medical Research Council's revised guidance on evaluating complex interventions, Moore *et al* (2015) note that an intervention may have limited effects because weaknesses in implementation may lead to inaccurate results relating

to efficacy. They recommend incorporating qualitative methods to understand any unknown barriers to implementation when testing feasibility of an intervention. The qualitative arm, in particular, of the HAPPI study has enabled exploration of challenges to implementation and revealed some unexpected barriers. This is an advantage of feasibility studies, as they can establish how an intervention might be optimally designed, prior to conducting a definitive trial (Public Health England, 2018). The identified challenges in implementing the HAPPI intervention will be discussed and potential solutions offered next.

8.6.1 Sharing decision-making and setting health goals

There has been major international and national policy moves towards shared decision making and personalisation of healthcare in recent decades in an attempt to promote self-determination. This is based on evidence that self-care can improve clinical outcomes and quality of life (Stacey et al., 2017). In the UK, this has led to the publication of clinical guidance to support shared decision making by the National Institute for Health and Care Excellence (2019b). One of the key expectations of the HAPPI intervention was its person-centred ethos with the clinician working in partnership with the participant to understand their health status and set personal goals. It was recognised that this approach, though favoured by the older people, carers and clinicians who designed the HAPPI intervention, might be difficult to achieve in practice. There is less evidence for shared decision-making in older people with complex health needs when additional challenges are faced including diminishing capacity to self-manage. With increasing frailty, the nature of decisions are more likely to be affected by resource availability, concordance and absence of support networks (Bunn et al., 2018). Preference for active participation declines with increasing numbers of long term conditions among older adults (Wolff & Boyd, 2015) and there is

evidence that the majority of older people do not associate ageing with the development of long-term conditions. Consequently, they do not recognise their role in self-managing to remain healthy and such challenges make self-care and goal setting more problematic (Netuveli & Blane, 2008).

In the HAPPI study, participants did not appear to acknowledge they had a role in shared decision-making and goal setting, but looked to the clinicians to lead this process. This appeared to be, in part, because they did not see themselves as patients in need of treatment and assistance from a nurse, regardless of their level of frailty. Community matrons expressed surprise and some frustration at participants' passivity and assumptions that they, as clinicians, would lead the decision-making process. Participants' had a lack of knowledge about their health conditions and complications of family and relationship dynamics also fed into the need to remain passive in relation to their health and care. This confirms the difficulties experienced by frail older people in actively participating in care planning and concurs with the findings of studies previously mentioned (Netuveli & Blane, 2008; Wolff & Boyd, 2015).

Van Hooft et al (2017) found that the intrinsic motivation of people with long-term conditions to participate is an important factor in self-management programmes and this motivation can be lacking in frail older people with poorer health and multimorbidity (Bleijenberg *et al.*, 2017b). Reporting on their recent qualitative study, La Grouw et al (2020) highlight how the diverse viewpoints of frail older people and clinicians may impact on the efficacy of shared decision making and care planning. They describe the key elements of this approach as needing clarity on both the “factual” and “normative” dimensions (La Grouw, Bannink & van Hout, 2020, p.2). The factual dimension comprises the facts about the person's problems and the normative dimension details the behaviour/action that can be taken to address the problem.

Frailty management is distinguished by a wide variety of factual and normative understandings. Clinicians may interpret frailty as a biomedical problem and propose a solution such as a new medication, whilst the older person may view frailty as a consequence of their social or environmental circumstances, such as loss of independence, and may propose a social solution, such as joining an exercise group. Neither solutions are wrong, but they do come from differing underpinning beliefs and norms, which may be difficult to reconcile. This fundamental difference in normative understanding can threaten the clinician/patient relationship and ultimately the success of the intervention. Le Grouw and colleagues recommend that partnership working can be enriched by participating in a dialogue in which both perspectives are acknowledged as meaningful and valuable (La Grouw, Bannink & van Hout, 2020). This accords with the HAPPI intervention which was based on a conversation guide, where the participant's concerns are explored and listened to and then the participant and the community matron worked together to agree and move towards goals which were meaningful to them both. Demonstrable changes included developing a plan of care and support, which persisted beyond the life of the intervention, focussing on contingency planning, developing a health information plan to share in an emergency and an agreed treatment escalation plan.

Whilst they were enthusiastic about working more proactively with patients earlier in the frailty trajectory, community matrons acknowledged that this was a different way of working from their normal practice. They acknowledged that working in a collaborative partnership with the participants was challenging and suggested that additional training was needed in motivational interviewing, a recognised technique for enabling patients to assess for themselves what is important and how change may be achieved (Miller & Rollnick, 2002). Daniels et al (2011) suggest that motivational interviewing

techniques may address difficulties older people have in engaging in self-management and goal-setting. The techniques, which include reflective listening, the use of open questions, reflecting, gentle probing and summarising, can be built into the assessment process to support clinicians in working in a more collaborative way. Thus, it is recommended that motivational interviewing training is provided for all clinicians who implement the intervention in a definitive trial. In addition, the intervention package will be structured, using the principles of motivational interviewing to enable clinicians to become more confident in their practice.

In summary, there were some unexpected and expected barriers to the implementation of the HAPPI intervention in real-life clinical practice. Conducting the feasibility trial gave the opportunity to understand the challenges in detail and to hear potential solutions from those who worked in primary care and experienced them first hand. This, combined with the evolving literature, has provided rich information for the design and planning of the definitive trial, which will be discussed further in section 8.7.

8.7 Achievement of feasibility criteria and progression to a definitive trial

It was gratifying to see that all criteria for progression to a definitive trial, as defined in the statistical analysis plan, were met (Table 6.16). Targets for site and participant recruitment, retention and adherence to the intervention were achieved, in addition, a primary outcome measure has been recommended for a definitive trial. However, this discussion chapter has also highlighted how the use of mixed-methods has proved helpful in identifying issues, which can be modified to enhance the chance of success of a definitive trial. These are summarised in Table 8.1.

Table 8.1: Lessons learned, challenges identified and recommendations for a definitive randomised controlled trial

Study activity	Lessons learned/challenges identified	Recommendations for a definitive trial
Trial Procedures		
Recruitment and retention of general practices as study sites.	Initial difficulties in generating interest in the trial and concern over lack of capacity in general practice to participate.	<ol style="list-style-type: none"> 1. Use local CRN and Primary Care Lead General Practitioner to publicise the trial and gain interest. 2. Fully estimate costs to the site of participation and ensure prompt payment or allocate funding for research assistant time to work with sites to complete study tasks. 3. Ensure automated site-reported data collection wherever possible.
Participant recruitment	Recruitment rates at individual sites was influenced by capacity and protocol deviations.	<ol style="list-style-type: none"> 1. Targeted research assistant support as above. 2. Additional training at site visit to ensure familiarisation with the trial protocol.
Lack of severely frail participants recruited.	eFI did not identify sufficient numbers of severely frail participants and more were likely to be screened out.	<ol style="list-style-type: none"> 1. Sample larger numbers of severely frail from the initial eFI list. 2. Include those who lack capacity to consent (but have a consultee). This would need to be approved by the NHS REC.
Communication of study aims.	Study participants reported lack of clarity about study aims and clinicians experienced difficulty in articulating aims.	<ol style="list-style-type: none"> 1. Development of an aide-memoire, a short plain English written explanation of study aims to be used by assessors and clinicians. 2. Wording to be incorporated into PIS so there is consistency of explanation across verbal and written processes.
Participant retention.	Participants valued the face-to face contact with the assessors which enhanced their experience of participation and may have led to enhanced retention.	<ol style="list-style-type: none"> 1. Participant-reported outcome measures are completed in a visit from the assessor, rather than by post or telephone interview. 2. Ensure all outcome measures assessment is completed in one visit at each study time point to reduce participant time commitment and burden.

Study activity	Lessons learned/challenges identified	Recommendations for a definitive trial
Collection of safety data	No adverse SAEs or AEs were reported during the trial period.	1. Develop guidance for assessors and clinicians in reporting AEs relating to components of the intervention which may cause harm, to ensure full reporting of AEs.
Trial Design		
Implementation of the intervention	Community matrons' clinical caseloads took priority over HAPPI intervention delivery. This led to delays.	1. Take a flexible approach to implementation at sites based on organisational challenges or opportunities. It may be appropriate for existing clinicians to deliver the intervention, or it may be more feasible to identify or employ "HAPPI" nurses who work exclusively on the study. 2. Consider using clinicians other than nurses to implement the intervention including a MDT approach.
Cluster randomisation	Cluster randomisation avoided contamination of the control group but unblinding of one assessor led to unblinding of allocation for the whole cluster.	1. Continue with written and verbal instructions to participants at consent and on randomisation. 2. Assessors to remind participants at the start of all study visits not to reveal allocation.
Follow-up period	Due to time constraints of this feasibility trial, follow-up was limited to three months and six months.	1. It is likely that a longer follow-up period is required to assess efficacy of the intervention. 2. Add an additional follow-up time point so that outcome measures are assessed at three-months, six-months and one year after consent.
Intervention		
Protocolisation of the intervention	HAPPI is a flexible, person-centred intervention, but there is a need to standardise for effective comparison between intervention and control groups.	1. Mandate the use of the conversation guide, personalised care and support plan and assessment tools for frailty severity, pain, functional independence, nutritional status and carer strain. 2. Ensure CRFs for the definitive trial allow capture data on other tools used in the intervention. 3. Localise "usual care". The fRCT has detailed the content of usual care based on the national primary care frailty contract. There may be local development of additional services and these need to be described for the definitive trial design.

Study activity	Lessons learned/challenges identified	Recommendations for a definitive trial
Facilitating shared decision-making and goal setting as part of the intervention.	It was difficult for participants to participate in a collaborative approach. Community matrons could be directive and struggled to share decision-making. Certain aspects of the care planning process were valued by participants.	<ol style="list-style-type: none"> 1. Provide training in motivational interviewing for clinicians implementing the intervention. 2. Provide a written guide to be used at intervention visits to support the principles of a collaborative approach to guide clinicians in their practice. 3. Ensure personalised care and support planning includes contingency and treatment escalation plans with a written copy that can be retained by the participant after the life of the trial.
Outcome measures		
Completion of outcome measures.	Completion of all outcome measures in one visit by assessor enabled high levels of completeness, but had the potential to introduce bias.	<ol style="list-style-type: none"> 1. Ensure face-to-face data collection in the participants' home. 2. Develop a written, protocol for asking the questions with standardised prompts to reduce potential bias.
Timing of outcome measures.	50% of outcome measures were completed outside of the protocol window of +/- 7 days of the due date.	<ol style="list-style-type: none"> 1. Lengthen protocol window to a range of 7 days before and 14 days after the due date.
Sensitivity to change of outcome measures.	All outcome measures appeared sensitive to change in the trial (with more limited evidence in the literature). There is likely to be less change improvement noted in severely frail due to existing morbidity/disability.	<ol style="list-style-type: none"> 1. Analyse data for moderately and severely frail participants separately to reduce heterogeneity of scores. 2. Conduct a detailed literature review to determine how much improvement in primary outcome can be expected in moderately and severely frail. Maybe that stabilisation of scores are appropriate

8.8 Towards a definitive RCT

The frailty literature has evolved during the time of this feasibility study and fellowship (2017-2020) primarily driven by international policy relating to frailty management in primary care (World Health Organization, 2017). Whilst the HAPPI study has allowed testing of study methods and intervention refinement, it is important to consider the findings of other studies that have been conducted concurrently. These findings have been incorporated into sections of this discussion to ensure transparency and that evidence is as current as possible.

Relevant specifically to the design of the definitive trial, three systematic reviews (Garrard *et al.*, 2020; Travers *et al.*, 2019; Van der Elst *et al.*, 2018) and one narrative synthesis (Frost *et al.*, 2020) have provided guidance on efficacy and content of CGA-based and other interventions to manage older people with complex conditions in primary care. In addition, the helpful findings of two studies have provided further information on methods of identification of frail people (Bleijenberg *et al.*, 2017b; Lee *et al.*, 2020). Garrard *et al.*'s systematic review (2020) demonstrates the scarcity of good quality studies into primary care CGA with only four studies included from 97 full texts screened, only one of which was nurse-led. The review concluded that primary care based CGA was acceptable but provided variable outcome benefit and, like other reviews (Beswick *et al.*, 2008), highlighted the difficulty of identifying appropriate frail patients. The other two systematic reviews (Travers *et al.*, 2019; Van der Elst *et al.*, 2018) included a variety of heterogeneous interventions, including CGA. These reviews were useful in that the majority of interventions did not appear to have a positive impact on outcomes, with the exception of a combination of muscle strength training and protein supplementation, which was effective in delaying or reversing

frailty and the easiest to implement in primary care. Finally, the narrative review (Frost *et al.*, 2020) demonstrated the positive impact of interventions that included self-management, assessment and care planning procedures and structured care pathways led by more experienced and qualified nurses. The findings from Frost's *et al.*'s work concur with the HAPPI study and the findings from Travers *et al.* regarding assessment for function/physical activity and nutritional supplementation will be included in the mandatory element of the intervention for the definitive trial. The HAPPI study community matrons were very experienced nurses with advanced clinical assessment skills. It will be important to ensure delivery of the intervention by similarly skilled clinicians in the definitive trial.

In this feasibility trial, the eFI was used to identify moderately and severely frail people to participate. As discussed, this method did not identify sufficient numbers of severely frail participants and there were some concerns about accuracy and number of false positives. This is a crucial factor for the success of the trial and thus it would seem appropriate to consider an additional participant identification method for the definitive trial, which will require many more participants. However, there is no definitive, feasible primary care frailty screening method as discussed in section 1.4.4. Bleijenberg *et al.* (2017b) reviewed the results from two RCTs and found that a nurse-led intervention had a positive impact on daily functioning in the oldest old population i.e. aged 80 years and over. It would seem appropriate to target this age group as frailty prevalence and severity increases with age (Gale, Westbury & Cooper, 2018). In addition, a very recent study from Canada has tested a novel approach to screening for frailty, which aims to identify those at highest risk to poor outcomes (Lee *et al.*, 2020). This dual trait approach based on gait speed and grip strength as a proxy for the Fried frailty phenotype has high levels of sensitivity and specificity and claims to be feasible in

primary care practice. In addition, they recommend only screening those aged 85 and over, plus those aged 75 years and over who have had two or more falls in the past six months. An advantage of this is that less people would need to be screened initially to obtain the study sample. It is, therefore, recommended that the definitive trial uses two methods of participant identification; eFI plus PRISMA-7 and the dual trait method (subject to the permission of the authors) and the age of participants is raised to 80 years. Consideration could then be given to analysis of the data from the two arms as comparison groups within the study.

Based on these changes from the original HAPPI study design, a model for the design of the definitive RCT has been developed (Figure 8.1). This builds on the findings of this study and informed by the new evidence from the very recent literature regarding study design and intervention content and delivery.

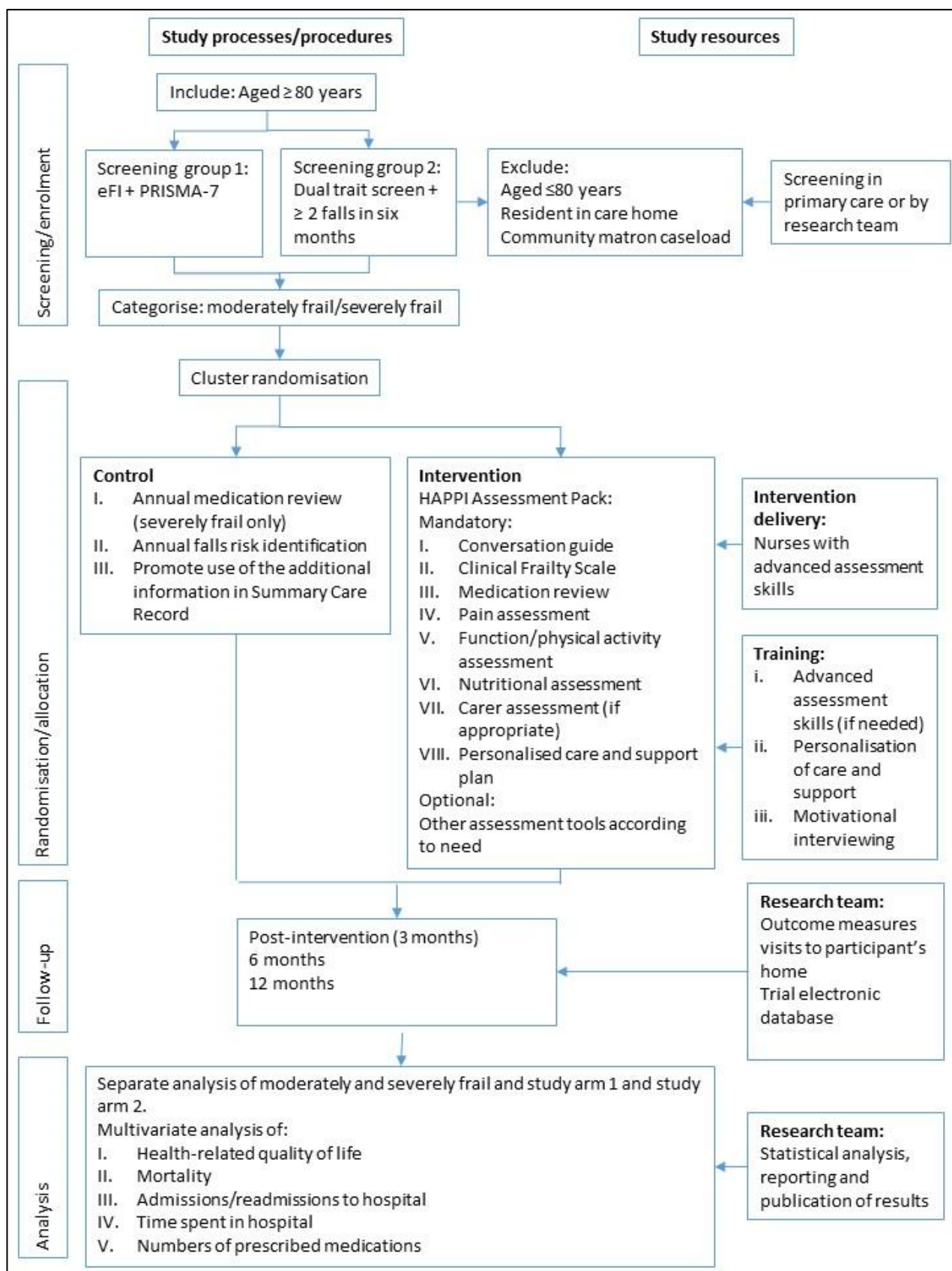


Figure 8.1: Model design for a definitive trial

8.9 Chapter summary

This fRCT with embedded qualitative component has demonstrated the feasibility of conducting an RCT of a nurse-led assessment and care planning intervention in primary care. In addition, it has provided valuable information to plan the design of the definitive trial. The next and final chapter will conclude this thesis with a summary of the research aims and their achievement, discussion of the overall contribution to knowledge, the limitations of the studies, provide recommendations for future research direction and implications for clinical practice and future research.

Chapter 9: Conclusions

9.1 Achievement of research aims

The HAPPI study aimed to develop, implement and test a nurse-led holistic assessment and care planning intervention and to determine important parameters for the design of a definitive RCT. The study was co-produced and designed in partnership with frail older people and carers through a PPI consultation. Consensus on the content and delivery of the intervention was achieved through an e-Delphi survey and further refined with the output from a research stakeholder group. Then an fRCT with embedded qualitative study determined the feasibility of the intervention and conducting the trial including its acceptability to patients, carers and clinicians. All research aims were achieved and both the feasibility of the intervention and conducting of a RCT were established.

In this final chapter, methodological limitations are discussed, and the implications of the findings are considered in relation to existing research and clinical practice. Specific contributions to new knowledge are reported and recommendations made for practical implementation and future research. The author's personal research journey is discussed with plans for the future.

9.2 Study limitations

There were limitations to both the e-Delphi study and the feasibility RCT. In the e-Delphi study, consensus levels for feasibility and importance were set at 75% based on discussion between the author and her supervisors in the absence of definitive guidance on setting consensus levels in Delphi studies. If consensus levels for feasibility had been set at 70%, rather than 75%, then an additional four components would have been included in the final CGA-based approach. Furthermore, if consensus

had been set at 70% agreement that a component was “feasible”, in addition to “very feasible” or “extremely feasible”, then all components would have met the criteria for feasibility. This decision on consensus led to the exclusion of important intervention components and required additional stakeholder consultation to resolve. Due to the explorative nature of this study, it may have been more appropriate to look to define and establish the preferred consensus level during the course of the survey rounds, rather than prior to commencement of the study.

Insufficient recruitment of severely frail participants was the main limitation of the feasibility RCT. This meant the study sample was not fully representative of the two levels of frailty the intervention can support and there was heterogeneity of responses with large ranges around the mean scores in all outcome measures as both levels were analysed as one group. These two issues must be addressed in the definitive trial by sampling more severely frail participants from the initial eFI lists, so that once eligibility criteria are applied there are still sufficient numbers to invite to participate. An alternative would be to consider an alternative frailty screening method, as discussed in section 8.7. It will be important to ensure clusters have similar proportions of moderately and severely frail participants so that comparisons can be made between the intervention and control group. This would allow data from the moderate and the frail groups to be analysed separately, however, there will need to be consideration of the larger sample size that will be required to achieve statistical power. If this is not deemed achievable in the definitive trial, there could be a secondary analysis undertaken of the moderately and severely frail participants’ data.

The small sample size of 60 participants is also acknowledged as a limitation in the fRCT and the study did not fully recruit to target in the timescale. However, 56

participants were recruited in ten months, thus, the actual monthly recruitment rate exceeded the target recruitment rate.

An additional limitation concerned the cluster design. Unblinding of one assessor by a participant revealing allocation, led to unblinding for the whole cluster. Further reinforcement of the need for participants to conceal allocation will be required in the definitive trial, as this is a known complication of the cluster design (Magill *et al.*, 2019). There is a trade-off here between the prevention of contamination, i.e. the receipt of the intervention amongst participants in the control arm, and the risk of unblinding of assessors inherent in cluster design. The cluster design prevented clinicians who were treating intervention participants from treating control participants, which is essential where the intervention is a new model of care involving elements that can be incorporated into usual practice. Therefore, despite this limitation, the cluster design is still recommended for a definitive trial.

The final limitation concerned the embedded qualitative study. It was planned to interview carers of participants in both the intervention and the control groups. However, it was not established at the consent visit whether or not participants had carers and, consequently, there was no way of identifying carers of the control group participants to invite for interview. This may not be relevant in the definitive trial as it is yet to be determined if there will be a qualitative component, but it did mean that the views of control group carers were not included and thus some important feedback on conduct of the trial from their perspective may have been missed.

9.3 Contributions to knowledge and clinical practice

9.3.1 Knowledge

The study has determined that it is feasible to conduct a clinical trial of a nurse-led assessment and care planning intervention for frail older people. It has established the content of the intervention and how to support effective implementation. Primary and secondary outcome measures have been evaluated and recommendations made for a definitive trial. This study is unique in its use of the eFI as a tool for identifying the target population and this has shown that it is a practical way to select moderately and severely frail participants. Limitations of the eFI have been explored and alternative frailty screening methods considered.

The author has been unable to source any other feasibility studies in this area in order to make comparisons with existing literature, however, as discussed in the evidence review of this thesis, randomised controlled trials of nurse-led CGA-based interventions have produced mixed results and recommended further research due to the heterogeneity of both the interventions and research methods. These studies have failed to evaluate the impact of a nurse-led, person-centred intervention for older people who live with frailty. While this feasibility trial was not designed to test the efficacy of the HAPPI intervention, it was able to test methods to address methodological deficiencies identified in the current literature with the aim of improving the chances of success of a definitive trial.

9.3.2 Clinical practice

The study has ascertained which components of the CGA can be delivered in primary care by nurses without specialist geriatrician involvement, in real life practice with the inherent time and capacity constraints. Potential barriers to implementation, which

include lack of training in promoting shared decision making and capacity to undertake proactive care alongside acute caseloads, have been identified and potential solutions recommended. The importance of a person-centred, flexible approach has been highlighted, but the trial has also identified the evidence-based mandatory content that has enabled protocolisation of the intervention for a future trial. It has also demonstrated that, by adopting a person centred approach, a holistic assessment can be offered to older people who live with frailty within the time constraints of primary care practice. It was exciting to see that this study has proved it is feasible to conduct a RCT, using an intervention that was well received by older people, carers and clinicians.

9.4 Final conclusions

This thesis charts my four-year research journey of personal development from a novice to a more proficient independent researcher able to plan, design and conduct research using a range of methodologies. It is important at this stage to reflect on my personal and professional growth. This has been an incredibly steep learning curve, however, the award of the NIHR Clinical Doctoral Fellowship meant that I was in the fortunate position of being able to design my own training and development programme and then put these skills into practice in my role as CI in the different phases of the study. With the unwavering support of with my supervisors and some lively, productive academic debate, I was able to advance my skills and develop expertise, which will progress my clinical academic career in future. At times, conducting three research studies across multiple sites using different methodologies seemed like I may have over-stretched my abilities. However, I viewed this as a unique opportunity to gain a deeper understanding of a range of research approaches and

learn how to truly mix methods, using complementarity to draw findings from the studies and unite them to answer the research questions. Practically, I learnt so much about research funding, regulations and procedures that will prepare me personally for future research design and planning. I gained important skills related to how to conduct research in demanding clinical settings, where real life constantly intrudes and where your study is not a priority to busy clinicians. Most importantly, I was able to explore how, by using mixed-methods, it is possible to provide a more enriched and profound evaluation of the implementation of a complex healthcare intervention in an under-researched population.

As a specialist nurse, I have witnessed the challenges faced by older people who live with frailty and the uncertainty that exists among clinicians concerning optimum support and management for this vulnerable group. These dilemmas are often compounded by the current climate of reducing budgets with limited time and capacity to care. This research, and its associated thesis, have attempted to address some of these concerns and complete initial, important steps to developing a new model of care, which may be clinically effective and feasible for the future. The practical issues of undertaking research in primary care have been examined and the qualitative work with older people, carers and nurses truly emphasised the different perspectives of the reality and complexity of partnership working between them.

Despite the challenges, a person-centred assessment and care planning intervention has been developed and the trial results make a unique contribution to the existing evidence base by showing that it is indeed feasible to conduct a RCT of the intervention in primary care, with nurses as the lead clinician. The next steps will be to explore the options for funding of the definitive trial and to consider further progression along a

clinical academic career pathway. Further research is now needed to determine the impact of the intervention on clinical outcomes and quality of life. I plan to apply for funding to conduct the definitive RCT, answering these questions and, ultimately, advancing nursing practice and improving patient outcomes.

People are living longer, but extra years of life are not always spent in good health. As the renowned actor Bette Davis once said: “Old age ain't no place for sissies” (Chandler, 2008, p.294) and there is no doubt that, as the decades pass, challenges to health and wellbeing increase. As a nurse, I witness courage, resilience and good humour every day among older people who live with frailty. I believe we owe our older citizens the best possible care and support, close to home, to remain independent and fulfilled as frailty develops. As one of the wonderful HAPPI participants said:

“It’s not just enough to be trying to get good results for people’s health but also for their happiness”.

Appendices

Appendix 1: Evidence review search strategy

Database: PubMed. Search date: 6/6/2019. Platform: OVID via University of Plymouth.		
Search	Query	Items found
#40	Search (#8 AND #11 AND #24 AND #30 AND #39)	103
#39	Search (#31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38)	519699
#38	Search "Office Nursing"[Mesh]	343
#37	Search "General Practice"[Mesh]	73263
#36	Search general practice[Title/Abstract]	36599
#35	Search (((("Community Health Services"[Mesh:NoExp]) OR "Community Health Nursing"[Mesh]	55356
#34	Search family medicine[Title/Abstract]	9951
#33	Search (primary care OR primary health care)	402727
#32	Search community health care[Title/Abstract]	1037
#31	Search community care[Title/Abstract]	4401
#30	Search (#27 OR #28 OR #29)	369170
#29	Search social function*[Title/Abstract]	13418
#28	Search ((wellbeing[Title/Abstract] OR well-being[Title/Abstract] OR well being[Title/Abstract]))	80386
#27	Search (#25 OR #26)	300459
#26	Search "Quality of Life"[Mesh]	176937
#25	Search quality of life[Title/Abstract]	244465
#24	Search (#14 OR #17 OR #18 OR #23)	117279
#23	Search (#21 AND #22)	6634
#22	Search nurs*[Title/Abstract]	438620
#21	Search (#18 OR #20)	9671
#20	Search geriatric assessment[Title/Abstract]	3557
#19	Search "Geriatric Assessment"[Mesh]	25427
#18	Search nursing intervention*[Title/Abstract]	6117
#17	Search (#15 OR #16)	41006
#16	Search "Patient Care Planning"[Mesh:NoExp]	37724
#15	Search "care plan*[Title/Abstract]	4162
#14	Search (#12 OR #13)	75828
#13	Search "Nursing Assessment"[Mesh]	32177
#12	Search nurs* assessment[Title/Abstract]	51445
#11	Search (#9 OR #10)	3493252
#10	Search ((elder*[Title/Abstract] OR aged[Title/Abstract] OR "older people"[Title/Abstract] OR "older person"[Title/Abstract] OR geriatric[Title/Abstract] OR senior[Title/Abstract] OR aging[Title/Abstract] OR "old age"[Title/Abstract]))	931836

Search	Query	Items found
#9	Search (("Aged"[Mesh]) OR "Aged, 80 and over"[Mesh])	2951024
#8	Search (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)	192870
#7	Search "Sarcopenia"[Mesh]	3256
#6	Search (("Frailty"[Mesh]) OR "Frail Elderly"[Mesh])	10950
#5	Search "complex needs"[Title/Abstract]	1334
#4	Search vulnerab*	125911
#3	Search fragil*[Title/Abstract]	39452
#2	Search sarcopenia[Title/Abstract]	6633
#1	Search frail*[Title/Abstract]	19079

Appendix 2: Supplementary Information 1, Delphi Paper Chapter 4

Figure Legend: Percentages, frequencies, mean scores and standard deviations for all components in round two

Component	Not at all important		Slightly important		Important		Fairly important		Very important		Total	Mean	SD
	%	n	%	n	%	n	%	n	%	n	n		
A system for data/information gathering e.g. past medical history, social circumstances	0.0%	0	0.0%	0	8.7%	2	4.4%	1	87.0%	20	23	5.0	0.6
Multi-disciplinary team discussion/review.	0.0%	0	0.0%	0	8.7%	2	4.4%	1	87.0%	20	23	5.0	0.6
Coordinated multidimensional assessment and care with an identified lead clinician	0.0%	0	4.4%	1	4.4%	1	4.4%	1	87.0%	20	23	5.0	0.7
A shared care record	0.0%	0	0.0%	0	4.4%	1	17.4%	4	78.3%	18	23	5.0	0.5
A timely response to crises	0.0%	0	0.0%	0	0.0%	0	9.1%	2	90.9%	20	22	5.0	0.3
A competent, well trained workforce who can deliver an assessment and care plan	0.0%	0	0.0%	0	4.4%	1	8.7%	2	87.0%	20	23	5.0	0.5
Assessment for the presence and severity of frailty	0.0%	0	0.0%	0	13.0%	3	13.0%	3	73.9%	17	23	5.0	0.7
Assessment of functional ability and activities of daily living including reablement	0.0%	0	0.0%	0	8.7%	2	17.4%	4	73.9%	17	23	5.0	0.6
Assessment of falls risk	0.0%	0	0.0%	0	9.5%	2	23.8%	5	66.7%	14	21	5.0	0.7
Assessment of cognition including identification of delirium and capacity assessment	0.0%	0	0.0%	0	8.7%	2	13.0%	3	78.3%	18	23	5.0	0.6
Assessment of mood and psychological well-being	0.0%	0	0.0%	0	17.4%	4	17.4%	4	65.2%	15	23	5.0	0.8
Assessment of pain	0.0%	0	0.0%	0	8.7%	2	13.0%	3	78.3%	18	23	5.0	0.6
Medication review including ability to self-administer, concordance and de-prescribing	0.0%	0	0.0%	0	8.7%	2	13.0%	3	78.3%	18	23	5.0	0.6
Assessment of nutritional status including hydration	0.0%	0	0.0%	0	17.4%	4	13.0%	3	69.6%	16	23	5.0	0.8
Assessment of social support including financial concerns, benefits entitlement, social network	0.0%	0	4.4%	1	13.0%	3	13.0%	3	69.6%	16	23	5.0	0.9
Assessment of vision, hearing and dentition	0.0%	0	4.4%	1	13.0%	3	4.4%	1	78.3%	18	23	5.0	0.9
Assessment of bladder and bowel function	0.0%	0	0.0%	0	9.5%	2	14.3%	3	76.2%	16	21	5.0	0.6
Environmental assessment including housing and equipment aimed at maximising independence	0.0%	0	0.0%	0	17.4%	4	4.4%	1	78.3%	18	23	5.0	0.8
Determining spiritual needs and support systems	0.0%	0	0.0%	0	26.1%	6	13.0%	3	60.9%	14	23	5.0	0.9
Sexual health assessment	0.0%	0	13.0%	3	30.4%	7	26.1%	6	30.4%	7	23	4.0	1.0
Exploring opportunities for employment/education/hobbies	4.4%	1	8.7%	2	30.4%	7	13.0%	3	43.5%	10	23	4.0	1.2
Optimising management of long term conditions/multimorbidity	0.0%	0	0.0%	0	13.6%	3	13.6%	3	72.7%	16	22	5.0	0.7
Advanced clinical assessment skills – physical examination and ordering investigations	0.0%	0	0.0%	0	17.4%	4	21.7%	5	60.9%	14	23	5.0	0.8
Problem/deficit identification	0.0%	0	4.6%	1	18.2%	4	9.1%	2	68.2%	15	22	5.0	0.9
Determining advance care preferences	0.0%	0	0.0%	0	8.7%	2	8.7%	2	82.6%	19	23	5.0	0.6
Escalation/contingency planning: actions for when the patient's condition deteriorates	0.0%	0	0.0%	0	8.7%	2	13.0%	3	78.3%	18	23	5.0	0.6
Establishing the patient's personal goals and where support is needed (person centred)	0.0%	0	4.4%	1	8.7%	2	4.4%	1	82.6%	19	23	5.0	0.8
Empowerment and self-management and enabling behavioural change	0.0%	0	4.4%	1	17.4%	4	26.1%	6	52.2%	12	23	5.0	0.9
Assessment of patient's ability to actively participate in care and planning	0.0%	0	4.4%	1	8.7%	2	13.0%	3	73.9%	17	23	5.0	0.8
Assessment of resilience and coping mechanisms – an asset based approach	4.4%	1	0.0%	0	13.0%	3	30.4%	7	52.2%	12	23	5.0	1.0
Assessment of carer's needs	0.0%	0	0.0%	0	17.4%	4	4.4%	1	78.3%	18	23	5.0	0.8
Establishing an individual's narrative by active listening/appreciative enquiry	0.0%	0	4.4%	1	17.4%	4	8.7%	2	69.6%	16	23	5.0	0.9
Agreeing and formulating a plan together based on shared decision making and the patient's needs	0.0%	0	4.4%	1	8.7%	2	4.4%	1	82.6%	19	23	5.0	0.8
Safeguarding this contract by documenting it in a co-created care or support plan: patient's agreement	0.0%	0	4.4%	1	13.0%	3	4.4%	1	78.3%	18	23	5.0	0.9
Monitoring response to the care and support plan	0.0%	0	0.0%	0	17.4%	4	4.4%	1	78.3%	18	23	5.0	0.8
Review and revising of the care and support plan	0.0%	0	0.0%	0	13.0%	3	8.7%	2	78.3%	18	23	5.0	0.7

Component	Not at all feasible		Slightly feasible		Feasible		Fairly feasible		Very feasible		Total	Mean	SD
	%	n	%	n	%	n	%	n	%	n	n		
A system for data/information gathering e.g. past medical history, social circumstances	0%	0	0.0%	0	40.0%	8	40.0%	8	20.0%	4	20	4.8	0.6
Multi-disciplinary team discussion/review.	0%	0	15.0%	3	30.0%	6	35.0%	7	20.0%	4	20	4.8	0.6
Coordinated multidimensional assessment and care with an identified lead clinician	0%	0	15.0%	3	50.0%	10	20.0%	4	15.0%	3	20	4.7	0.7
A shared care record	10%	2	40.0%	8	15.0%	3	30.0%	6	5.0%	1	20	4.7	0.5
A timely response to crises	0%	0	10.5%	2	47.4%	9	31.6%	6	10.5%	2	19	4.9	0.3
A competent, well trained workforce who can deliver an assessment and care plan	0%	0	15.0%	3	20.0%	4	50.0%	10	15.0%	3	20	4.8	0.5
Assessment for the presence and severity of frailty	0%	0	9.1%	2	27.3%	6	27.3%	6	36.4%	8	22	3.9	1.0
Assessment of functional ability and activities of daily living including reablement plan	0%	0	4.8%	1	23.8%	5	38.1%	8	33.3%	7	21	4.0	0.9
Assessment of falls risk	0%	0	4.6%	1	31.8%	7	13.6%	3	50.0%	11	22	4.1	1.0
Assessment of cognition including identification of delirium and capacity assessment	0%	0	13.6%	3	27.3%	6	31.8%	7	27.3%	6	22	3.7	1.0
Assessment of mood and psychological well-being	0%	0	22.7%	5	31.8%	7	27.3%	6	18.2%	4	22	3.4	1.0
Assessment of pain	0%	0	4.6%	1	13.6%	3	27.3%	6	54.6%	12	22	4.3	0.9
Medication review including ability to self-administer, concordance and de-prescribing	0%	0	4.6%	1	45.5%	10	40.9%	9	9.1%	2	22	3.6	0.7
Assessment of nutritional status including hydration	0%	0	4.6%	1	36.4%	8	27.3%	6	31.8%	7	22	3.9	0.9
Assessment of social support including financial concerns, benefits entitlement, social network	0%	0	13.6%	3	50.0%	11	27.3%	6	9.1%	2	22	3.3	0.8
Assessment of vision, hearing and dentition	0%	0	19.1%	4	38.1%	8	23.8%	5	19.1%	4	21	3.4	1.0
Assessment of bladder and bowel function	0%	0	13.6%	3	27.3%	6	31.8%	7	27.3%	6	22	3.7	1.0
Environmental assessment including housing and equipment aimed at maximising independence	0%	0	4.6%	1	63.6%	14	18.2%	4	13.6%	3	22	3.4	0.8
Determining spiritual needs and support systems	5%	1	13.6%	3	31.8%	7	27.3%	6	22.7%	5	22	3.5	1.1
Sexual health assessment	5%	1	18.2%	4	63.6%	14	4.6%	1	9.1%	2	22	3.0	0.9
Exploring opportunities for employment/education/hobbies	5%	1	14.3%	3	47.6%	10	19.1%	4	14.3%	3	21	3.2	1.0
Optimising management of long term conditions/multimorbidity	0%	0	9.1%	2	36.4%	8	50.0%	11	4.6%	1	22	3.5	0.7
Advanced clinical assessment skills – physical examination and ordering investigations	0%	0	18.2%	4	45.5%	10	13.6%	3	22.7%	5	22	3.4	1.0
Problem/deficit identification	0%	0	9.5%	2	28.6%	6	23.8%	5	38.1%	8	21	3.9	1.0
Determining advance care preferences	0%	0	13.6%	3	50.0%	11	22.7%	5	13.6%	3	22	3.4	0.9
Escalation/contingency planning: actions for when the patient's condition deteriorates	0%	0	9.1%	2	36.4%	8	45.5%	10	9.1%	2	22	3.6	0.8
Establishing the patient's personal goals and where support is needed (person centred)	0%	0	9.1%	2	31.8%	7	22.7%	5	36.4%	8	22	3.9	1.0
Empowerment and self-management and enabling behavioural change	0%	0	22.7%	5	54.6%	12	18.2%	4	4.6%	1	22	3.1	0.8
Assessment of patient's ability to actively participate in care and planning	0%	0	4.6%	1	36.4%	8	40.9%	9	18.2%	4	22	3.7	0.8
Assessment of resilience and coping mechanisms – an asset based approach	9%	2	18.2%	4	40.9%	9	13.6%	3	18.2%	4	22	3.1	1.2
Assessment of carer's needs	5%	1	4.6%	1	40.9%	9	22.7%	5	27.3%	6	22	3.6	1.1
Establishing an individual's narrative by active listening/appreciative enquiry	0%	0	9.1%	2	54.6%	12	18.2%	4	18.2%	4	22	3.5	0.9
Agreeing and formulating a plan together based on shared decision making and the patient's goals	5%	1	4.6%	1	36.4%	8	31.8%	7	22.7%	5	22	3.6	1.0
Safeguarding this contract by documenting it in a co-created care or support plan: patient and professional agreement	0%	0	18.2%	4	40.9%	9	31.8%	7	9.1%	2	22	3.3	0.9
Monitoring response to the care and support plan	0%	0	18.2%	4	40.9%	9	22.7%	5	18.2%	4	22	3.4	1.0
Review and revising of the care and support plan	0%	0	4.6%	1	50.0%	11	22.7%	5	22.7%	5	22	3.6	0.9

Appendix 3: Supplementary Information 2, Delphi Paper Chapter 4

Figure Legend: Percentages, frequencies, mean scores and standard deviations for all components in round three

Component	Not at all important		Slightly important		Important		Fairly important		Very important		Total	Mean	SD
	%	n	%	n	%	n	%	n	%	n	n		
A system for data/information gathering e.g. past medical history, social	0.0%	0	0.0%	0	0.0%	0	0.0%	0	100.0%	24	24	5.0	0.0
Multi-disciplinary team discussion/review	0.0%	0	0.0%	0	0.0%	0	8.3%	2	91.7%	22	24	4.9	0.3
Coordinated multidimensional assessment and care with an identified le	0.0%	0	0.0%	0	4.2%	1	12.5%	3	83.3%	20	24	4.8	0.6
A shared care record	0.0%	0	0.0%	0	8.3%	2	16.7%	4	75.0%	18	24	4.7	0.6
A timely response to crises	0.0%	0	0.0%	0	0.0%	0	0.0%	0	100.0%	24	24	5.0	0.0
A competent, well trained workforce who can deliver an assessment and	0.0%	0	0.0%	0	4.2%	1	0.0%	0	95.8%	23	24	4.9	0.4
Assessment for the presence and severity of frailty	0.0%	0	0.0%	0	12.5%	3	12.5%	3	75.0%	18	24	4.6	0.7
Assessment of functional ability and activities of daily living including re-	0.0%	0	0.0%	0	4.2%	1	16.7%	4	79.2%	19	24	4.8	0.6
Assessment of falls risk	0.0%	0	4.2%	1	0.0%	0	20.8%	5	75.0%	18	24	4.6	0.7
Assessment of cognition including identification of delirium and capacity	0.0%	0	0.0%	0	0.0%	0	25.0%	6	75.0%	18	24	4.8	0.4
Assessment of mood and psychological well-being	0.0%	0	0.0%	0	0.0%	0	12.5%	3	87.5%	21	24	4.9	0.3
Assessment of pain	0.0%	0	0.0%	0	0.0%	0	4.2%	1	95.8%	23	24	5.0	0.2
Medication review including ability to self-administer, concordance and	0.0%	0	0.0%	0	0.0%	0	4.2%	1	95.8%	23	24	5.0	0.2
Assessment of nutritional status including hydration	0.0%	0	0.0%	0	4.2%	1	12.5%	3	83.3%	20	24	4.8	0.5
Assessment of social support including financial concerns, benefits entitl	0.0%	0	0.0%	0	4.2%	1	4.2%	1	91.7%	22	24	4.9	0.4
Assessment of vision, hearing and dentition	0.0%	0	0.0%	0	0.0%	0	12.5%	3	87.5%	21	24	4.9	0.3
Assessment of bladder and bowel function	0.0%	0	0.0%	0	0.0%	0	20.8%	5	79.2%	19	24	4.8	0.7
Environmental assessment including housing and equipment aimed at m	0.0%	0	0.0%	0	4.2%	1	8.3%	2	87.5%	21	24	4.8	0.5
Determining spiritual needs and support systems	0.0%	0	0.0%	0	4.2%	1	29.2%	7	66.7%	16	24	4.6	0.6
Sexual health assessment	0.0%	0	4.2%	1	12.5%	3	33.3%	8	50.0%	12	24	4.3	0.8
Exploring opportunities for employment/education/hobbies	0.0%	0	4.2%	1	12.5%	3	50.0%	12	33.3%	8	24	4.1	0.8
Optimising management of long term conditions/multimorbidity	0.0%	0	0.0%	0	0.0%	0	8.7%	2	91.3%	21	23	4.9	0.3
Advanced clinical assessment skills - physical examination and ordering i	0.0%	0	4.2%	1	8.3%	2	20.8%	5	66.7%	16	24	4.6	0.8
Problem/deficit identification	0.0%	0	0.0%	0	8.3%	2	16.7%	4	75.0%	18	24	4.7	0.6
Determining advance care/end of life preferences	0.0%	0	0.0%	0	0.0%	0	8.3%	2	91.7%	22	24	4.9	0.3
Escalation/contingency planning: actions for when the patient's conditio	0.0%	0	0.0%	0	0.0%	0	16.7%	4	83.3%	20	24	4.8	0.4
Establishing the patient's personal goals and where support is needed (p	0.0%	0	0.0%	0	4.2%	1	8.3%	2	87.5%	21	24	4.8	0.5
Empowerment and self-management and enabling behavioural change	0.0%	0	0.0%	0	4.2%	1	20.8%	5	75.0%	18	24	4.7	0.5
Assessment of patient's ability to actively participate in care and planning	0.0%	0	0.0%	0	12.5%	3	4.2%	1	83.3%	20	24	4.7	0.7
Assessment of resilience and coping mechanisms - an asset based approa	0.0%	0	0.0%	0	4.2%	1	25.0%	6	70.8%	17	24	4.7	0.6
Assessment of carers needs	0.0%	0	0.0%	0	0.0%	0	12.5%	3	87.5%	21	24	4.9	0.3
Establishing an individual's narrative by active listening/appreciative enc	0.0%	0	4.2%	1	4.2%	1	12.5%	3	79.2%	19	24	4.7	0.8
Agreeing and formulating a plan together based on shared decision maki	0.0%	0	0.0%	0	8.3%	2	12.5%	3	79.2%	19	24	4.7	0.6
Safeguarding this contract by documenting it in a co-created care or supp	0.0%	0	0.0%	0	12.5%	3	12.5%	3	75.0%	18	24	4.6	0.7
Monitoring response to the care and support plan	0.0%	0	0.0%	0	16.7%	4	0.0%	0	83.3%	20	24	4.7	0.8
Review and revising of the care and support plan	0.0%	0	0.0%	0	8.3%	2	8.3%	2	83.3%	20	24	4.8	0.6

Component	Not at all feasible		Slightly feasible		Feasible		Fairly feasible		Very feasible		Total	Mean	SD
	%	n	%	n	%	n	%	n	%	n	n		
A system for data/information gathering e.g. past medical history, social	0.0%	0	0.0%	0	19.1%	4	28.6%	6	52.4%	11	21	4.3	0.7
Multi-disciplinary team discussion/review	0.0%	0	0.0%	0	23.8%	5	57.1%	12	19.1%	4	21	3.9	0.6
Coordinated multidimensional assessment and care with an identified le	0.0%	0	9.5%	2	42.9%	9	42.9%	9	4.8%	1	21	3.4	0.7
A shared care record	0.0%	0	38.1%	8	42.9%	9	19.1%	4	0.0%	0	21	2.8	0.8
A timely response to crises	0.0%	0	4.8%	1	47.6%	10	28.6%	6	19.1%	4	21	3.5	0.8
A competent, well trained workforce who can deliver an assessment and	0.0%	0	4.8%	1	42.9%	9	42.9%	9	9.5%	2	21	0.1	0.8
Assessment for the presence and severity of frailty	0.0%	0	4.8%	1	14.3%	3	42.9%	9	38.1%	8	21	4.0	0.9
Assessment of functional ability and activities of daily living including re-	0.0%	0	0.0%	0	14.3%	3	52.4%	11	33.3%	7	21	4.1	0.7
Assessment of falls risk	0.0%	0	0.0%	0	19.1%	4	23.8%	5	57.1%	12	21	4.4	0.8
Assessment of cognition including identification of delirium and capacity	0.0%	0	4.8%	1	23.8%	5	42.9%	9	28.6%	6	21	3.9	0.8
Assessment of mood and psychological well-being	0.0%	0	4.8%	1	28.6%	6	38.1%	8	28.6%	6	21	3.9	0.8
Assessment of pain	0.0%	0	0.0%	0	4.8%	1	33.3%	7	61.9%	13	21	4.5	0.7
Medication review including ability to self-administer, concordance and	0.0%	0	0.0%	0	19.1%	4	57.1%	12	23.8%	5	21	4.0	0.7
Assessment of nutritional status including hydration	0.0%	0	0.0%	0	14.3%	3	38.1%	8	47.6%	10	21	4.3	0.8
Assessment of social support including financial concerns, benefits entitl	0.0%	0	4.8%	1	47.6%	10	38.1%	8	9.5%	2	21	3.4	0.8
Assessment of vision, hearing and dentition	0.0%	0	0.0%	0	33.3%	7	66.7%	14	0.0%	0	21	3.6	0.5
Assessment of bladder and bowel function	0.0%	0	0.0%	0	19.1%	4	61.9%	13	19.1%	4	21	4.0	0.6
Environmental assessment including housing and equipment aimed at m	0.0%	0	4.8%	1	42.9%	9	38.1%	8	14.3%	3	21	3.6	0.8
Determining spiritual needs and support systems	0.0%	0	4.8%	1	38.1%	8	33.3%	7	23.8%	5	21	3.7	0.9
Sexual health assessment	0.0%	0	23.8%	5	47.6%	10	19.1%	4	9.5%	2	21	3.1	0.9
Exploring opportunities for employment/education/hobbies	0.0%	0	9.5%	2	52.4%	11	23.8%	5	14.3%	3	21	3.4	0.9
Optimising management of long term conditions/multimorbidity	0.0%	0	0.0%	0	28.6%	6	66.7%	14	4.8%	1	21	3.8	0.6
Advanced clinical assessment skills - physical examination and ordering i	0.0%	0	9.5%	2	33.3%	7	38.1%	8	19.1%	4	21	3.5	0.9
Problem/deficit identification	0.0%	0	4.8%	1	23.8%	5	42.9%	9	28.6%	6	21	3.9	0.9
Determining advance care/end of life preferences	0.0%	0	9.5%	2	19.1%	4	42.9%	9	28.6%	6	21	3.8	0.9
Escalation/contingency planning: actions for when the patient's condition	0.0%	0	0.0%	0	38.1%	8	42.9%	9	19.1%	4	21	3.9	0.8
Establishing the patient's personal goals and where support is needed (p	0.0%	0	0.0%	0	19.1%	4	47.6%	10	33.3%	7	21	4.8	0.5
Empowerment and self-management and enabling behavioural change	0.0%	0	9.5%	2	57.1%	12	19.1%	4	14.3%	3	21	3.3	0.8
Assessment of patient's ability to actively participate in care and planning	0.0%	0	0.0%	0	23.8%	5	61.9%	13	14.3%	3	21	3.8	0.7
Assessment of resilience and coping mechanisms - an asset based approa	0.0%	0	9.5%	2	57.1%	12	33.3%	7	0.0%	0	21	3.2	0.6
Assessment of carers needs	0.0%	0	9.5%	2	23.8%	5	42.9%	9	23.8%	5	21	3.9	0.9
Establishing an individual's narrative by active listening/appreciative end	0.0%	0	9.5%	2	38.1%	8	33.3%	7	19.1%	4	21	3.6	0.9
Agreeing and formulating a plan together based on shared decision maki	0.0%	0	0.0%	0	42.9%	9	23.8%	5	33.3%	7	21	3.9	0.9
Safeguarding this contract by documenting it in a co-created care or supp	4.8%	1	0.0%	0	61.9%	13	23.8%	5	9.5%	2	21	3.4	0.9
Monitoring response to the care and support plan	0.0%	0	4.8%	1	52.4%	11	33.3%	7	9.5%	2	21	3.5	0.7
Review and revising of the care and support plan	4.8%	1	0.0%	0	33.3%	7	38.1%	8	23.8%	5	21	3.8	1.0

Appendix 4: HAPPI Conversation Guide

The HAPPI Study Conversation Guide

Name	
Address	
ID Number	

What matters to you?

Prompts: Usual day, social networks, activities, joining in – helps & challenges, family , friends, social circle, support network, personal care, your home, finances, benefits

Do you have any health conditions that worry you? How do you manage them?

Prompts: well-being, LTCs, frailty, pain effects on lifestyle/exercise/mobility, falls, eating and drinking, sleep, hearing/eyesight/dentition, bladder and bowel function/sexual health, depression, anxiety, cognitive impairment

Do you feel safe in your home? Is there anything regarding your home that concerns you?

Functional abilities at home, environmental hazards, equipment needs, maximising independence, re-ablement needs

What medication do you take and does it cause you any problems?

Prompts: medication review, consider polypharmacy, need for de-prescribing

Is there anything you would like to change and what might help you or prevent you making the changes?

Prompts: problem/deficit identification, resilience and coping mechanisms.

What would you like to happen if your health deteriorated?

Health and care packages, support, what happens in an emergency, escalation plan, advance care plan, spiritual needs and support mechanisms

Who is around to support you?

Informal and formal care, consider assessment of carers needs. Would the person benefit from an advocate or IMCA?

What can we achieve together? (Use SMART – Specific, Measurable, Achievable, Realistic, Timely)

Personal goals or aspirations support needed for empowerment, ability to participate in care planning.

Appendix 5: Notes of research stakeholder meeting

The HAPPI Study: Research Stakeholder Meeting

St Austell Printworks, Boardroom 31/01/2018, 09.30-11.30.

In Attendance: Marie Prior, Frailty and Non-Medical Prescribing Lead, Cornwall Foundation NHS Trust (MP)

Kerry Crowther, Falls Lead, Cornwall Foundation NHS Trust (KC)

Jos Latour, Professor in Clinical Nursing, Associate Head of School – Research, School of Nursing and Midwifery, Plymouth University (JL)

Helen Lyndon, NIHR Clinical Doctoral Research Fellow, Plymouth University, Nurse Consultant Older People Cornwall Foundation NHS Trust (HL)

Apologies: Tracy Hind, Workforce Transformation Lead, Cornwall Foundation NHS Trust

Professor Sir Roger Boyle, PPI Group Chair, Roseland Surgery

Mrs Hazel Boyle, PPI Representative

Dr Julie Tomlinson, St Austell Group Practice

Notes of the Meeting

No.	Item
1	Introductions Everyone introduced themselves and HL updated on apologies and arrangements to meet with other stakeholder group members who could not attend today outside of the meeting.
2	Introduction to the overall HAPPI Study HL gave a brief overview of the study, progress to date and explained the purpose of the stakeholder group, which is to review the results of the e-Delphi survey and refine and agree the final components and design of the HAPPI intervention. HL stressed that this intervention needs to be feasible to deliver in clinical practice in primary care, but also likely to improve outcomes for frail older people.
3	Review and refinement of the HAPPI intervention HL shared the results of the e-Delphi survey (Appendix 1) and indicated which components had reached consensus and which had not. The group reviewed each component in detail and debated which should be included and which should not. It was agreed that the principles of the intervention would be based in person-centred care and the following are key principles that make the intervention unique and different to current care for this population: a) The person will not be referred (as in current community matron (CM) practice) but will be approached proactively following

	<p>identification using the electronic frailty index and PRISMA7 screening tool. The CM will visit without first gaining any past medical history or other information about the person's health from the general practice record and initiate an "unbiased, open dialogue" with the person. Any issues/problems/deficits will be generated from this dialogue and the assessment and care-planning intervention will develop from this point.</p> <ul style="list-style-type: none"> b) There will be an ongoing development and review of a support plan in partnership with the person and carer (if appropriate). c) Outcome measures will focus on responsiveness to change/completeness of the intervention and discharge plans; what is different after the intervention is complete? d) The intervention will be based on a "conversation guide" rather than a prescriptive template. Assessments reflecting the results of the e-Delphi will be available to be used if they are appropriate for that person's needs/problems. <p>The group reviewed each component of the e-Delphi results and discussed and agreed whether it should be included or not within the conversation guide or assessment pack and how it should be presented to ensure ease of use and feasibility:</p> <p>Care Structures/Processes</p> <p>These components included access to a shared system for information gathering (clinical record), multi-disciplinary team discussion/review, a timely response to crises and a competent, well-trained workforce to deliver the intervention. It was agreed that these components formed important feasibility outcomes for the trial, but were not elements of the assessment process. HL agreed to include these as feasibility outcome measures.</p> <p>Nursing/Advanced Clinical Practice</p> <p>It was agreed that tools to assess presence/severity of frailty, falls risk, pain, medication review, nutrition/hydration/dentition, vision/hearing, bladder and bowel function including sexual health assessment, optimising long-term condition management and assessment of functional capacity should all be included in the assessment pack.</p> <p>Further discussion concluded that the conversation guide should also include prompts for problem/deficit identification, advance care planning and escalation/contingency planning. There is a personalised care template under development in the county and MP agreed to share it with HL for use in the trial.</p> <p>It was agreed that the need for advanced assessment skills was to be included in the care structures/processes section as a feasibility outcome measure for the trial.</p> <p>Mental Health</p> <p>It was agreed that assessment of cognition should be included in assessment of falls risk to avoid duplication of assessment. Prompts to</p>
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	<p>investigate mood and psychological wellbeing including anxiety and depression should be part of the conversation guide with more detailed assessments available in the assessment pack.</p> <p>Social and Environmental Circumstances It was agreed that this should be re-worded as “Home and Safety” and be included within prompts in the conversation guide such as “do you feel safe at home”, “is there anything regarding your home that concerns you?” An exploration of loneliness and social isolation will be added to the mood and psychological well-being section.</p> <p>It was agreed that exploration of spiritual needs and support systems would be included in advance care planning discussions.</p> <p>Although assessment of carers needs did not reach consensus for feasibility in the e-Delphi survey, it was strongly felt by stakeholders that this is an essential element of the intervention and would be included in the conversation guide as a prompt.</p> <p>Personalised Care and Support Planning It was agreed to combine and include the first, second, sixth and seventh components in this section as essential pillars of personalised care and support planning. Assessment of resilience and ability to participate in care planning was felt to be an important element of the intervention and so it was agreed to include it in the conversation guide prompts.</p> <p>The final three components of the development of a plan, monitoring response and reviewing the plan were agreed as important outcome measures for the trial.</p>
4	<p>Final decisions and wrap-up HL thanked all those for their invaluable input. The following actions were agreed:</p> <ul style="list-style-type: none"> a) HL to develop a draft of the conversation guide and assessment pack and circulate to group members for final comment. b) HL to circulate the next draft of the trial protocol for comments. c) MP and KC kindly agreed to sit on the Trial Steering Committee. HL to send a doodle poll of dates for the first meeting in April 2018. d) MP to share the personalised care and support planning template with HL for use in the trial.

Appendix 6: HAPPI Assessment Pack Contents

Full copies of all assessments can be found on the HAPPI study website:

<https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi>

Domain	Page no
Physical Health Assessments	
Assessment for the presence and severity of frailty	
1. Gait Speed Test	1
2. Clinical Frailty Scale	2
Assessment of falls risk and bone health	
1. Multifactorial Risk Assessment Tool (MFRAT)	3
2. FRAX	4
Assessment of pain	
1. Numeric pain scale	5
2. Pain assessment record	6
3. Abbey Pain Scale (for use in patients with cognitive impairment)	7
Medication review	
1. Medication review summary	8
2. STOPP-START medication review tool	9
Assessment of nutritional status including hydration	
1. MUST 5 Step Guidance	37
2. MUST Flowchart	38
3. MUST Full Screening Tool	39
Assessment of vision, hearing and dentition	
1. RCP Bedside Vision Check	46
2. Whispered Voice Test	59
Assessment of bladder and bowel function	
1. Clinical Checklist for Lower Urinary Tract Symptoms	60
2. ICIQ Bladder Diary	62
3. Self-Assessment of Your Urinary Problems	63
4. Bowel Assessment Form	68
5. Clinical Checklist for Faecal Incontinence	69
Optimising management of long term conditions/multimorbidity and Problem/deficit identification	
1. BGS CGA and Problem List	71

Domain	Page no
Determining advance care/end of life preferences <ol style="list-style-type: none"> 1. CFT Treatment Escalation Plan Policy 2. CFT Treatment Escalation Plan Booklet 	74 108
Home, family and Safety	
Assessment of functional ability and activities of daily living including re-ablement <ol style="list-style-type: none"> 1. Barthel Index 	120
Loneliness/social isolation <ol style="list-style-type: none"> 1. UCLA 3-Item Loneliness Scale 	123
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Appendix 7: HAPPI fRCT Protocol

STUDY PROTOCOL

A cluster randomised, controlled feasibility study of a nurse-led, holistic assessment and care planning intervention for older people living with frailty in primary care.

The Holistic Assessment and care Planning
in Partnership Intervention Study
[HAPPI]



[V 2.1]

[18/03/2019]

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This protocol has regard for the HRA guidance and order of content

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1. SIGNATURE PAGE

Role	Name	Signature	Date
Chief Investigator	Helen Lyndon		15/05/2018
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2. KEY CONTACT DETAILS

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3. LIST OF ABBREVIATIONS

AE	Adverse Event
BGS	British Geriatrics Society
CGA	Comprehensive Geriatric Assessment
CI	Chief Investigator
CM	Community Matron
CRF	Case Report Form
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
eFI	Electronic Frailty Index
GCP	Good Clinical Practice
GP	General Practitioner
ICF	Informed Consent Form
ISRCTN	International Standard Randomised Controlled Trials Number
LTC	Long term condition
MCA	Mental capacity Act
NHS R&D	National Health Service Research & Development
PenCTU	Peninsula Clinical Trials Unit
PIS	Participant Information Sheet
PPI	Patient and public involvement
PRISMA7	Program of Research to Integrate Services for the Maintenance of Autonomy – 7 item tool
QA	Quality Assurance
QC	Quality Control
RA	Research Assistant
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
SWCRN	South West Clinical Research Network
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

4. STUDY SUMMARY

Study Title	The Holistic Assessment and care Planning in Partnership Intervention Study [HAPPI]: A cluster randomised, controlled feasibility study of a nurse-led, holistic assessment and care planning intervention for older people living with frailty in primary care.
Study Design	Feasibility, cluster randomised controlled trial with embedded qualitative study.
Study Participants	People aged 65 years and over who are moderately or severely frail.
Study Setting	General Practice populations in Cornwall, UK.
Intervention	Delivery of the HAPPI intervention by trained community matrons in accordance with the conversation guide and assessment pack to ensure treatment fidelity. The intervention will be an individualised assessment and care planning process including development of person-centred goals supported by planning and relevant referrals. It will be carried out at the participant's home. Documentation of the intervention including assessment, individualised care and support plan and evidence of any referrals will be recorded using a standardised document/computerised template.
Control	Participants in the control group will receive usual care. This cannot be standardised as approaches to care of older people with frailty varies in general practice. This may include the management of various long-term conditions, referrals to other services, prescribing of medications and routine vaccinations. As part of the feasibility trial, components of usual care will be captured using a standardised proforma in order to describe for the future definitive trial.
Study duration	24 months
Nº of participants	60
Aims and Objectives	The primary aim of this cluster randomised, controlled feasibility study of a nurse-led Holistic Assessment and care Planning in Partnership Intervention (HAPPI) is to determine the feasibility of delivering the intervention in primary care to older people with frailty and to test potential trial methods to inform the design of a definitive randomised controlled trial (RCT). Objectives a-g will be met within the feasibility randomised controlled trial:

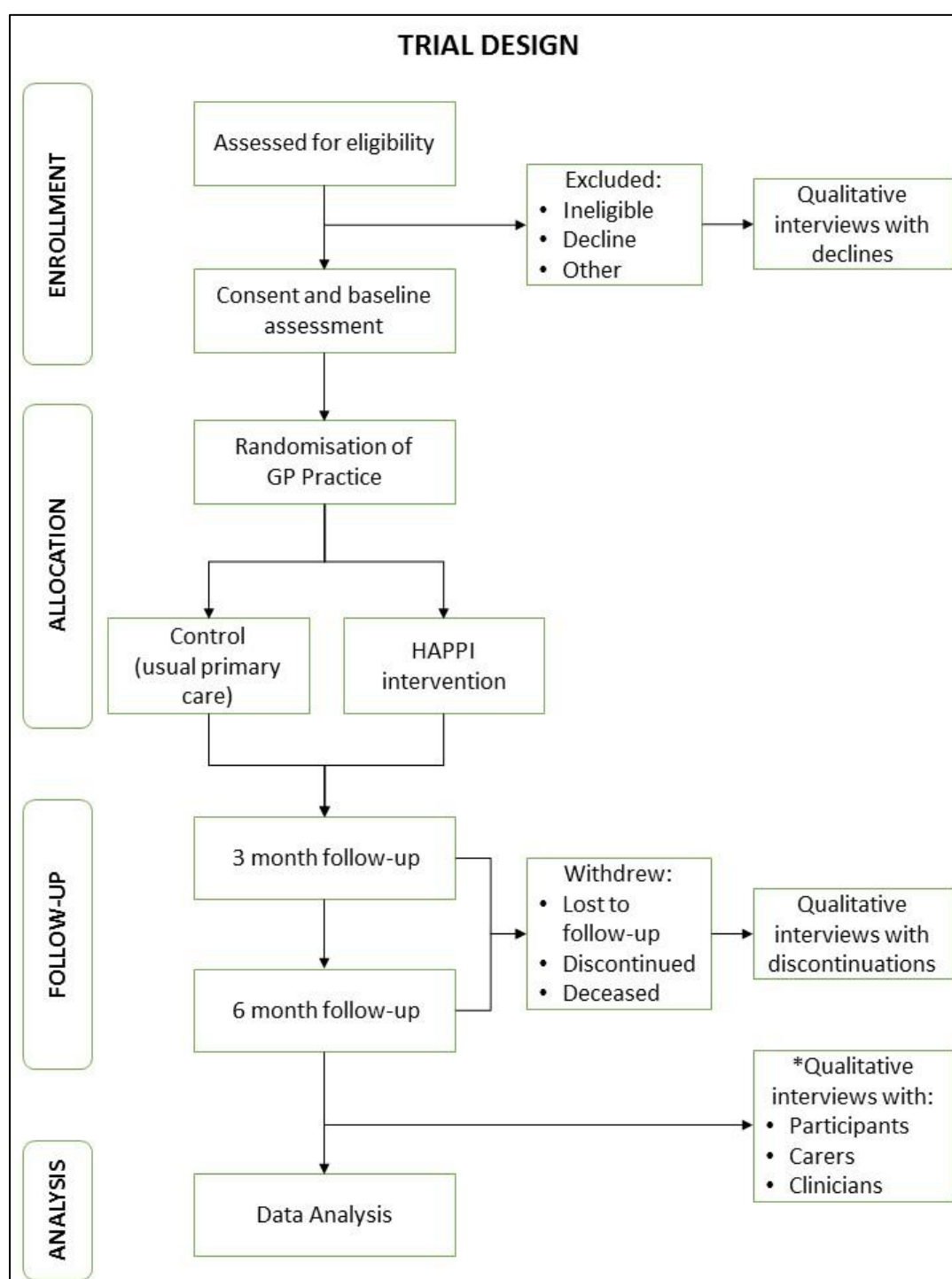
	<ul style="list-style-type: none"> a. To assess compliance with the HAPPI intervention. b. To verify that proposed outcome measurement and follow-up schedules are feasible to collect. c. To determine achievable targets recruitment and follow-up rates. d. To evaluate methods of recruitment using the electronic frailty index (eFI). e. To evaluate characteristics and feasibility of the proposed outcome measures and to determine suitable outcome measures for the definitive trial. Outcome measures to be evaluated have been taken from the ICHOM Older Persons Reference Guide (1). f. To calculate standard deviation of the outcome measures to estimate sample size for the definitive trial. g. To assess availability of clinical data and time needed to collect and analyse data required for numeric outcome measures. h. To explore factors that will enable future economic evaluation alongside the main trial. <p>Objectives h-j will be met within the embedded qualitative study:</p> <ul style="list-style-type: none"> i. To determine acceptability of the intervention to patients, carers and clinicians in primary care. j. To assess barriers to delivery of the HAPPI intervention e.g. any operational difficulties within the community matron service. k. To evaluate clinicians' willingness to identify, recruit and randomise eligible patients, and willingness of patients to be recruited and randomised. l. To determine acceptability of trial processes and collection of outcome measures to participants.
Outcomes	<p>The outcomes relate to feasibility of the intervention, feasibility of conducting the trial and assessing different potential primary and secondary outcomes of the future trial.</p> <p>Feasibility of the intervention</p> <ul style="list-style-type: none"> a. Numbers of completed HAPPI intervention conversation guides and personalised care plan templates b. Number of staff moving between intervention and control GP practices <p>Feasibility of conducting the trial</p> <ul style="list-style-type: none"> c. Number of GP practices expressing an interest in participating

	<p>d. Number of GP practices screened for selection and reasons for non-selection</p> <p>e. Number of GP practice withdrawing from the study, timing and reason for withdrawal</p> <p>f. Number of GP practices failing to progress through implementation milestones and reasons for failure</p> <p>g. Number of GP practices withdrawing during the implementation and delivery phases</p> <p>h. Numbers of participants screened as eligible, recruited, consented and followed up</p> <p>i. Numbers of participants identified using the electronic frailty index (eFI)</p> <p>j. Number of and timing of participant withdrawals from follow-up data collection, reasons for withdrawal, number of and timing of losses to follow-up</p> <p>Assessing different potential primary and secondary outcomes of the future trial</p> <p>k. Numbers of potential primary and secondary outcome measures completed at baseline and follow-up intervals</p> <p>l. Numbers of missing items for each potential primary and secondary outcome at each time-point</p> <p>m. Estimation of the feasibility of collecting data to estimate cost-effectiveness; EQ-5D-5L; add-on for economic evaluation.</p> <p>n. Assessment of the following outcome measure instruments:</p> <ul style="list-style-type: none"> • Review of usual care practice, using a clinical note review of control participants • Level of care at home received measured by participant self-reporting • Polypharmacy – number of medications prescribed and participant perception of adverse effects • Number of falls measured by participant self-reporting • Levels of loneliness and isolation measured by UCLA 3-Item Loneliness Scale • Physical health and mobility, level of pain, mood and emotional health and health-related quality of life measured by the Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36)
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	<ul style="list-style-type: none"> • Confidence in own ability to manage health and in role as participants in care measured by the Health Foundation LTC6 questionnaire • Mortality; date and cause of death obtained from the clinical record • Number of hospital admissions, readmissions and total number of days spent in hospital obtained from the clinical record <p>All outcome measures will be conducted at baseline (following randomisation), three months (post intervention) and six months.</p>
Inclusion criteria	<p>Potential participants will be eligible for the study provided they are:</p> <ul style="list-style-type: none"> f. Aged 65 years and over g. Moderately frail: Electronic Frailty Index (eFI) >0.24 to 0.36 or severely frail (eFI > 0.36) h. Frailty confirmed by PRISMA7 instrument i. Able to give informed consent j. Living in own home/supported living accommodation
Exclusion criteria	<p>Potential participants meeting any of the following criteria will be excluded from study participation:</p> <ul style="list-style-type: none"> a. Fit or mildly frail (eFI 0.13 – 0.24) b. Lives in a care home c. Patients in receipt of palliative care, on gold standards framework register or where clinician feels they have limited life expectancy d. Lacks mental capacity to give informed consent e. Patients already on the caseload of a Community Matron.
Key Milestones	<p>May 2018: Set up phase and recruit GP practices</p> <p>November 2018: Participant identification and eligibility check</p> <p>January 2019: Consent and baseline measures</p> <p>March 2019: Intervention</p> <p>June 2019: 3-month follow-up data collection</p> <p>November 2019: 6-month follow-up data collection</p>

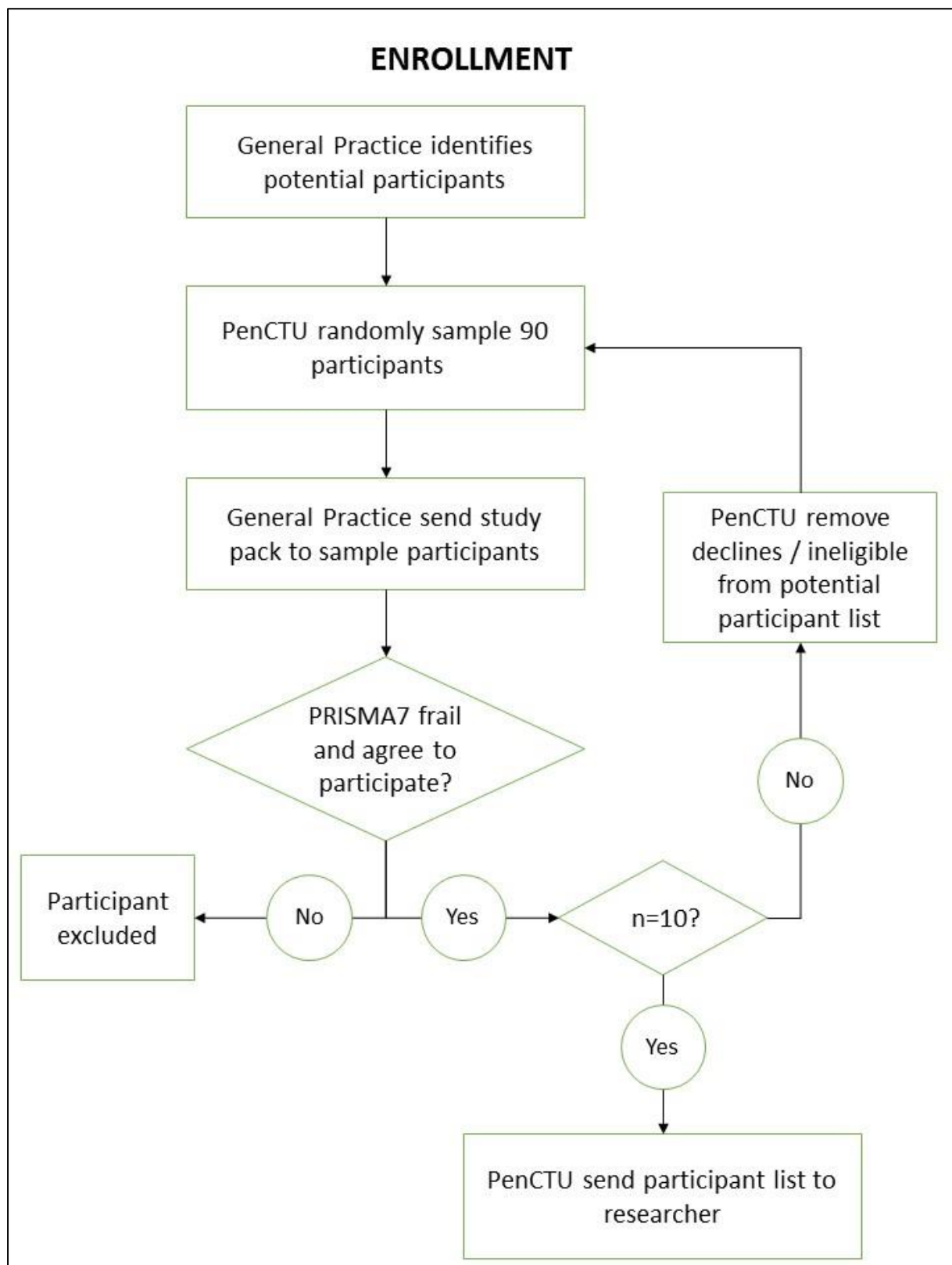
5. TRIAL FLOW DIAGRAMS

Figure 1: Flow diagram of the trial design



*Qualitative interviews will be conducted with selected a maximum of six participants, four carers and a maximum of six community matrons

Figure 2: Flow diagram of the enrolment process



6. BACKGROUND AND RATIONALE FOR THE PROPOSED STUDY

6.1 Understanding Frailty

Healthcare support needs to change radically to better meet the needs of the ageing population. In the UK, the number of people aged 65+ is projected to rise by over 41% in the next 17 years to over 16 million. By 2040, nearly one in four people in the UK (24%) will be aged 65 or over (2). In older people, limiting disability is often preceded by a state characterised by reduced capacity to respond to stressors, caused by a decline in functional reserves (3,4). This condition is called frailty. There are multiple definitions of frailty in the literature but the most common characteristics are summarised by Roriguez-Manas and Fried as being:

“an age associated, biological syndrome characterised by decreased biological reserves, due to dysregulation of several physiological systems, which puts an individual at risk when facing minor stressors, and is associated with poor outcomes (i.e. disability, death, and hospitalisation)” (5)

As frailty progresses, individuals become more susceptible to developing conditions known as frailty syndromes, which include multiple falls, acute confusion/delirium, sudden loss of mobility and incontinence (6). These events often result in admission to hospital, following which frail older people experience increased lengths of stay and are more prone to complications such as developing hospital acquired infections, pressure sores, delirium and loss of independence (7).

6.2 Frailty as a Long Term Condition

Some authors have advocated a move towards the early identification, diagnosis and management of frailty in order to improve outcomes, prevent or delay deterioration and reduce health and social care costs (8,9). Frailty is rarely formally diagnosed in any speciality other than geriatric medicine and is not yet recognised as a long-term condition (LTC) in primary care, despite the introduction in 2014 of diagnostic read codes by the Health and Social Care Information Centre. De Lepeleire et al (8) advocate the management of frailty in primary care settings. However, they acknowledge that the identification of frailty and application to clinical practice in this area are under-developed. Given its high prevalence, most of the on-going frailty management will, in all likelihood, fall into the remit of primary care in the future. Further research is therefore urgently needed to explore feasibility and resource issues as it is unlikely that there is sufficient capacity or appropriate skills and knowledge in primary care settings to adequately manage the numbers of frail patients. However, if an achievable preventive model of care is developed, primary care is the ideal setting to implement a more person-centred approach because of the integrated nature of primary and community care and the opportunities to interact with patients in their home environment (10).

6.3 The Management of Frailty

One evidence-based approach to the management of moderate and severe frailty is the Comprehensive Geriatric Assessment (CGA). CGA is a multidimensional, interdisciplinary diagnostic process to determine the medical, psychological and functional capabilities of a frail older person in order to develop a coordinated and integrated individualised care plan for treatment and long-term follow up in partnership with the patient and the carers (11). This approach is part of routine care and well evidenced in the hospital setting within the

speciality of geriatric medicine but not well established in other healthcare settings such as primary care.

6.4 Frailty Interventions in Primary Care

In 2014 the British Geriatrics Society (BGS) (11) suggested that a primary care led 'holistic review' by a GP or specialist nurse may enable more frail older people to access services out of hospital, however, as previously discussed, it is not clear whether the acute hospital CGA framework is immediately transferable. In 2014, Stijen (12) evaluated practice nurse-led CGA and found prohibitive issues for the primary care team including lack of skills, time constraints and ineffective targeting of the frail population. A study evaluating nurse-led CGA in primary care reported significant barriers including lack of skills, time constraints and ineffective targeting of the frail population (13). A recent review noted a lack of an agreed implementation model and concerns of workforce capacity in the current UK primary care model (14).

The BGS have suggested other considerations that are missing from the traditional CGA framework, such as treatment escalation and advanced care planning (11). These considerations would appear to be highly relevant as part of a CGA intervention delivered in a primary care setting where the clinician has a more long-term and person-centred relationship with the patient. A recent review of person-centred care concluded that while there is no universal definition of the concept, there are well recognised behaviours displayed by nurses that promote person-centeredness, such as engaging with the patient as a partner and shared decision making (15). These behaviours and their foundation in nurses' approaches to care would appear to make nurses the ideal clinician to carry out CGA/holistic review in a primary care setting.

6.5 Beyond Best Practice and This Study

To meet the challenges of the increasingly frail and older population and to provide proactive, holistic care close to home, there is a need for a standardised intervention that can be implemented in primary care, which provides value for money, is not time consuming and has a high level of sensitivity to enable primary care resource to be targeted at patients who will most benefit from the intervention. If a primary care led 'holistic review' is to become a reality, the burden of completion and frail patient outcomes require further research as to the feasibility, acceptability, effectiveness and scalability. Informed by the existing literature and PPI engagement, the proposed study seeks to develop a primary care intervention that contains cost and clinically effective components of the acute CGA framework and determines if this intervention is suitable for nurse-led delivery.

During an initial phase of this research, an e-Delphi survey was conducted to gain consensus among stakeholders on the components of the intervention and any existing skills and knowledge deficits. Using these data, a component map was formulated whereby the components were mapped to patient need using the best available evidence to ascertain those which may be feasible in terms of clinical and cost effectiveness. After mapping the outcomes, a conversation guide and assessment pack to structure the intervention were developed to be used in this feasibility randomised controlled trial (RCT).

7. AIMS AND OBJECTIVES

7.1 Aims

The primary aim of this cluster randomised, controlled feasibility study of a nurse-led Holistic Assessment and care Planning in Partnership Intervention (HAPPI) is to determine the

feasibility of delivering the intervention in primary care to older people with frailty and to test potential trial methods to inform the design of a definitive randomised controlled trial (RCT).

7.2 Objectives

Objectives a-h will be met within the feasibility randomised controlled trial:

- a) To assess compliance with the HAPPI intervention.
- b) To verify that proposed outcome measurement and follow-up schedules are feasible to collect.
- c) To determine achievable targets for recruitment and follow-up rates.
- d) To evaluate method of recruitment using the electronic frailty index (eFI).
- e) To evaluate characteristics and feasibility of the proposed outcome measures and to determine suitable outcome measures for the definitive trial. Outcome measures to be evaluated have been taken from the ICHOM Older Persons Reference Guide (1).
- f) To calculate standard deviation of the outcome measures to estimate sample size for the definitive trial.
- g) To assess availability of clinical data and time needed to collect and analyse data required for numeric outcome measures.
- h) To explore factors that will enable future economic evaluation alongside the main trial.

Objectives i-l will be met within the embedded qualitative study:

- i) To determine acceptability of the intervention to patients, carers and clinicians in primary care.
- j) To assess barriers to delivery of the HAPPI intervention e.g. any operational difficulties within the community matron service.
- k) To evaluate clinicians' willingness to identify, recruit and randomise eligible patients, and willingness of patients to be recruited and randomised.
- l) To determine acceptability of trial processes and collection of outcome measures to participants.

8. TRIAL DESIGN

The trial is a pragmatic, cluster randomised, controlled feasibility trial with embedded qualitative study aiming to recruit 60 participants from general practices in Cornwall. Figure 1 details the trial design. Cluster randomisation by general practice has been chosen to test methods to reduce between-group contamination and which may lead to biased estimates of

effect size in the main trial and so this feasibility trial aims to evaluate this randomisation method. Half of the general practices will be allocated to the intervention and half to the control arm of the study, so that patients of individual practices will either receive the intervention or usual primary care. By randomising at general practice level, it will avoid the potential for “intervention-creep” between the intervention and the control group. In the area under study, community matrons (CMs) are attached to specific general practices and so individual CMs would only visit participants in the control or the intervention group, never both. As the HAPPI is an intervention that aims to impact on staff skills, knowledge and clinical practice, it is important to ensure separation of the control and intervention groups in this way.

CI/RAs will have no role in initial screening or approach, this will be carried out by the clinical care team at the General Practice (PIC). The CI/RAs will only have access to personal data with the participant’s permission from the invitation letter so they can contact them to carry out consent/baseline assessment. Patient screening, consent, recruitment and collection of outcome measures will be undertaken by the CI or RAs (Cornwall Foundation Trust Research Nurses or SWCRN Research Nurses) who have no role in the delivery of care or treatment. The RAs will remain blind to treatment allocation until completion of the six-month outcome measures and will be unblinded for the qualitative interviews. Contamination will be assessed by frequent monitoring of staff movement and recording clinical practices through regular contact with GP practices carried out by the CI. If staff movement between intervention and control practices occurs, the date and nature of the change will be noted.

8.1 Study Setting and GP Practice Eligibility

It is anticipated that there will be six GP practices involved in this study, located in Cornwall, UK. The following factors will be used to determine suitability of practices to participate in this study:

- d. The practice use the electronic frailty index (eFI) to identify their moderately and severely frail population
- e. The practice are willing to fulfil the requirements of the study relating to screening and recruitment with the support of the SWCRN
- f. There is at least one CM attached to the practice who is willing to deliver the HAPPI intervention

GP practices registering an interest in the trial will be invited to complete a Participant Identification Centre Feasibility Questionnaire and will be offered a visit by the CI/SWCRN Nurse. Practices deemed suitable to implement and deliver HAPPI (demonstrated by fulfilling the above criteria) will be invited to take part in the study. Reasons for non-selection of practices will be fully documented.

8.2 Recruitment

8.2.1 Initial Screening and Enrolment Process

The enrolment process is detailed in Figure 2, and represents the procedure conducted by GP practices and PenCTU to identify and recruit eligible participants. Under the terms of the NHS England General Practice Contract 2017/18 (16), practices are required to identify patients aged 65 years and over, who are living with moderate or severe frailty, among their practice population. Practices use an appropriate evidenced based tool such as the eFI (17). The eFI is a computerised algorithm that is integral to the majority of general practice electronic clinical

records and is used to identify and grade severity of frailty based on a cumulative deficit model on the basis of a range of variables that include symptoms, signs, diseases, disabilities and abnormal laboratory values (17). A practice administrator will run the eFI as a database search and this will classify the entire practice population into fit, mildly frail, moderately frail and severely frail people. The output from the eFI, combined with the application of the trial inclusion/exclusion criteria, will identify initial potential participants for the trial. Based on available evidence it is likely that, for an average-sized practice (14,000 practice population), the eFI will identify approximately 1000 moderately and 500 severely frail people.

8.2.2 Sampling

A flow diagram of the enrolment and sampling process can be seen in Figure 2. In order to create the initial enrolment sample, the practice administrator at each practice will create a list of potential eligible participants aged 65 years and over identified by running the eFI, indicating those who are moderately and those who are severely frail. Eligibility criteria of living at home and not in receipt of palliative care/limited life expectancy will be applied at the general practice and PenCTU will use stratified sampling to identify 90 potential participants from the eFI list, 45 in the moderate and 45 in the severely frail categories. The eFI is not a clinical diagnostic tool, rather it is a population risk stratification tool, therefore, a further step is required to make a diagnosis of frailty and confirm eligibility. In this trial, that diagnosis will be confirmed by the completion of the PRISMA7 questionnaire (18). An invitation to participate in the trial and PRISMA7 will be sent to the 90 people. Interested patients will be invited to return the completed PRISMA7 and a completed portion of the invitation to participate in the stamped addressed envelope to the CI. However, if this sampling strategy does not identify 10 eligible participants then sampling will be repeated

until 10 participants per practice are recruited. It is estimated that inviting approximately 90 patients will enable 10 per practice to be recruited to the trial in the time allowed for recruitment.

Names and contact details of people who have expressed an interest in participation, and where frailty has been confirmed by the PRISMA7, will be passed to the CI by the practice administrator by secure email (NHS mail). If people express an interest in participating but then are found not eligible, or maximum numbers for recruitment have been achieved, the CI will telephone the person to thank them for their interest in the study and explain why they have not been recruited.

For those eligible and to be recruited, a period of 24 hours will be left between completion of PRISMA7 and receiving the reply before contacting to arrange to gain consent. This gives potential participants time to consider whether or not they wish to enter the trial. They will then be contacted by the CI/RA by telephone and an appointment made for a visit at home or in the surgery to provide choice and minimise participant burden. During this consultation, the participant will be given the opportunity to ask further questions about the study before consent is obtained and baseline assessments carried out.

8.2.3 Demographic Detail

The following demographic data will be collected. These will be in addition to the outcome measures described in Table 1 for all participants. The demographic data will be recorded on a CRF by the CI or RA.

- *Demographic data:* date of birth, gender, marital status
- *Frailty status:* eFI and PRISMA7 score

8.2.4 Registration

Once informed consent has been received, and confirmation of eligibility and baseline data have been collected, the CI/RA will then register the participant on the study database using a unique username and password log-in details, entering initials and gender and will assign a study number. In line with CONSORT guidelines for randomised pilot and feasibility studies (19), and in order to report the generalisability of the results, study- specific screening logs will be kept, with anonymised details of those potential participants who the research team approached to be considered for entry to the study, but who were not recruited or randomised. The web-based screening log will be completed by the CI or another authorised delegate.

Anonymised information on participants that have consented but are not recruited for

CONSORT reporting will include:

- a. Age
- b. Gender
- c. Frailty status: eFI and PRISMA7 scores
- d. Reason not eligible for trial participation, or if they are eligible but declined.

8.3 Baseline Assessments

Once consent has been received, baseline assessment of outcome measures will be undertaken with the participants. All baseline assessments will be carried out in one session and at the same time as consent is obtained to minimise burden of multiple contacts for participants. They will be undertaken by the CI or authorised delegate (RAs). Consent and baseline outcome measures will be collected in the participant's place of residence and it is estimated that this consent and data collection visit will be approximately 60 minutes

duration. Support and additional time/visit will be offered to participants who may need suffer fatigue, cognitive impairment etc. As a feasibility study, any difficulties will be noted and adjustment made to the design of the main trial.

The assessor will record the results of the baseline assessments on the case report form (CRF) and enter the results into a secure password protected web-based system. This will generate an email for the community matron who will be carrying out the intervention informing that he/she can contact the participant and arrange the first visit in accordance with the intervention guide. All outcome measures are detailed in Table 1.

Table 1: Outcome Measures, Data Sources and Collection Measures

Variable	Objective	Data Source	Outcome Measure and Collection Method
BASELINE CLINICAL FACTORS			
Function	To investigate the use of the BI in this setting and for this population as a measure of function by collecting completion rates and expressed views on acceptability to participants.	Participant reported	Barthel Index of Activities of Daily Living (20) Participants will self-report based on their abilities on the day of assessment.
Level of care received	To investigate if it is possible to collect data on level of care received and how best to report this.	Participant reported	Participants will self-report on current local authority provided home support.
Polypharmacy	To investigate if it is possible to collect data on number of medications and how best to report this.	Clinical data	Total number of medications prescribed obtained from the clinical record.
	To investigate the use of participant self-reporting on adverse effects of medication by collecting completion rates and expressed views on acceptability to participants.	Participant reported	Participants will self-report any adverse effects of medications experienced.
Number of falls	To investigate participant self-reporting as an accurate method of estimating number of falls experienced.	Participant reported	Participants will self-report number of falls in the past 12 months including those that resulted in contact with health services and outcome.
SYMPTOMS/FUNCTIONING/HEALTH-RELATED QUALITY OF LIFE			
Physical health and mobility	To investigate the use of the SF-36 in this setting and for this population as a measure of physical health and mobility by collecting completion rates and expressed views on acceptability to participants.	Participant reported	Questions 1-16 of Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36) (21) Participants will self-report based on their activities on the day of assessment.
Loneliness and social isolation	To investigate the use of the UCLA 3-Item Loneliness Scale in this setting and for this	Participant reported	UCLA 3-Item Loneliness Scale (22)

	population as a measure of social isolation and loneliness by collecting completion rates and expressed views on acceptability to participants .		Participants will self-report their experience on the day of assessment.
Pain	To investigate the use of the SF-36 in this setting and for this population as a measure of levels of pain by collecting completion rates and expressed views on acceptability to participants.	Participant reported	Questions 21 and 22 of Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36) Participants will self-report their experience on the day of assessment.
Mood and emotional health	To investigate the use of the SF-36 in this setting and for this population as a measure of mood and emotional health by collecting completion rates and expressed views on acceptability to participants.	Participant reported	Questions 17-20 of Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36) Participants will self-report their experience on the day of assessment.
Health-related quality of life	To investigate the use of the SF-36 in this setting and for this population as a measure of health-related quality of life by collecting completion rates and expressed views on acceptability to participants.	Participant reported	Questions 23-36 of Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36) Participants will self-report their experience on the day of assessment.
PERSON-CENTRED CARE			
Confidence in own ability to manage own health and in role as a participant in care	To investigate the use of the LTC6 in this setting and for this population as a measure of confidence by collecting completion rates and expressed views on acceptability to participants.	Participant reported	Health Foundation LTC6 questionnaire (23) Participants will self-report their experience on the day of assessment.
CLINICAL STATUS			
Mortality	To investigate if it is possible to collect data on mortality and how best to report this.	Clinical data	Date and cause of death obtained from the clinical record.
Numbers of unplanned hospital admissions, re-admissions	To investigate if it is possible to collect data on numbers of admissions, re-admissions and total time spent in hospital and how best to report this.	Clinical data	All obtained from the clinical record: How many times the participant has been admitted

and total time spent in hospital			to hospital as an emergency in the past 12 months. How many times has the participant been readmitted to hospital within 30 days of a previous admission. Total length of stay in hospital within the past 12 months.
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8.4 Intervention

Participants in the intervention group (n=30) will receive the HAPPI intervention delivered by a CM who has received training in delivering the intervention. In Cornwall, CMs are experienced nurses with advanced assessment and prescribing skills and, therefore have the required skills set to deliver the assessment and care planning intervention. CMs are attached to individual general practices and employed by the community services NHS Trust (Cornwall Foundation NHS Trust). In order to ensure a standardised approach, training will be given prior to delivering the intervention using a training package delivered by face-to-face training by the CI.

The holistic assessment and care planning intervention (HAPPI) will encompass the following key principles that make the intervention unique and different to current care for this population:

- a. The person will not be referred in crisis (as in current CM practice) but will be approached proactively following identification using the eFI and PRISMA7 screening tool.
- b. The CM will visit without first gaining any past medical history or other information about the person's health from the general practice record and initiate an "unbiased, open dialogue" with the person. Any issues/problems/deficits will be generated from this dialogue and the assessment and care-planning intervention will develop from this point.
- c. There will be an ongoing development and review of a support plan in partnership with the person and carer (if appropriate).

- d. Outcome measures will focus on responsiveness to change/completeness of the intervention and discharge plans; what is different after the intervention is complete.
- e. The intervention will be based on a “conversation guide” rather than a prescriptive assessment template. Assessment tools will be available to be used if they are appropriate for that person’s needs/problems.

A conversation guide, assessment pack and personalised support plan template have been developed to support delivery of the intervention and ensure treatment fidelity by detailing the content of the intervention and how it should be delivered. The intervention will be carried out in the participant’s home and it is expected that it will consist of one assessment visit and up to six care planning visits conducted over a maximum of 12 weeks. For the purpose of the trial, the minimum “dose” of the intervention will be defined as one assessment visit and at least two care planning visits. Documentation of the intervention, including assessment, support plan and evidence of any referrals, will be recorded using a standardised document/computerised template, which will be stored at in the clinical record at the Community Matron’s base with a copy in the electronic general practice clinical record.

8.5 Control

Participants in the control group (n=30) will receive usual care. This cannot be standardised as approaches to care of older people with frailty varies in general practice (11). This may include the management of various long-term conditions, referrals to other services, prescribing of medications and routine vaccinations. As part of the feasibility trial, components of usual care will be captured in order to standardise for the future definitive RCT using a standardised template.

8.6 Outcomes

The primary outcomes relate to feasibility of the intervention, feasibility of conducting the trial and assessing different potential primary and secondary outcomes of the future trial.

8.6.1 Feasibility of the Intervention

- a) Numbers of completed HAPPI intervention conversation guides and personalised care plan templates
- b) Assess degree of contamination by number of staff moving between intervention and control practices

8.6.2 Feasibility of Conducting the Trial

- a) Number of GP practices expressing an interest in participating
- b) Number of GP practices screened for selection and reasons for non-selection
- c) Number of GP practices withdrawing from the study, timing and reason for withdrawal
- d) Number of GP practices failing to progress through implementation milestones and reasons for failure
- e) Number of GP practices withdrawing during the implementation and delivery phases
- f) Numbers of participants screened as eligible, recruited, consented and followed up
- g) Numbers of participants identified using the electronic frailty index (eFI)
- h) Number of and timing of participant withdrawals from follow-up data collection, reasons for withdrawal, number of and timing of losses to follow-up

8.6.3 Potential Primary and Secondary Outcomes

- a) Numbers of potential primary and secondary outcome measures completed at baseline and follow-up intervals
- b) Numbers of missing items for each potential primary and secondary outcome at each time-point
- c) Estimation of the feasibility of collecting data to estimate cost-effectiveness; EQ-5D-5L; add-on for economic evaluation.
- d) Assessment of the following outcome measure instruments:
 - Review of usual care practice, using a clinical note review of control participants
 - Level of care at home received measured by participant self-reporting
 - Polypharmacy – number of medications prescribed and participant perception of adverse effects
 - Number of falls measured by participant self-reporting
 - Levels of loneliness and isolation measured by UCLA 3-Item Loneliness Scale
 - Physical health and mobility, level of pain, mood and emotional health and health-related quality of life measured by the Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36) (Table 1)

- Confidence in own ability to manage health and in role as participants in care measured by the Health Foundation LTC6 questionnaire
- Mortality; date and cause of death obtained from the clinical record
- Number of hospital admissions, readmissions and total number of days spent in hospital obtained from the clinical record

All potential clinician and self-reported primary and secondary outcome measures will be collected at baseline (following randomisation), three months (post intervention) and six months.

As a feasibility trial, process evaluation is a key part of the intervention development process to enable conclusions to be drawn about the strengths and weaknesses of a trial. The Medical Research Council guidance highlights the need to clarify causal mechanisms and identify contextual factors associated with variation in outcomes. It highlights the importance of capturing fidelity (whether the intervention was delivered as intended); dose (the quantity of intervention implemented) and reach (whether the intended audience comes into contact with the intervention, and how).

Fidelity will be measured using several mechanisms: nurses delivering the intervention will receive standardised training and use a conversation guide, assessment pack and personalised support plan template as a framework for the intervention. They will record the content of their intervention and any adverse events related to the intervention or any intercurrent illnesses in the CRF.

9. TRIAL PARTICIPANT SELECTION

9.1 Inclusion Criteria

Potential participants will be eligible for the study provided they are:

- a. Aged 65 years and over
- b. Moderately frail: Electronic Frailty Index (eFI) >0.24 to 0.36 or severely frail (eFI > 0.36)
- c. Frailty confirmed by PRISMA7 instrument
- d. Able to give informed consent
- e. Lives in own home/supported living accommodation

9.2 Exclusion Criteria

Potential participants meeting any of the following criteria will be excluded from study participation:

- a. Fit or mildly frail (eFI 0.13 – 0.24)
- b. Lives in a care home
- c. Patients in receipt of palliative care, on gold standards framework register or where clinician feels they have limited life expectancy
- d. Lacks mental capacity to consent to participate
- e. Patients already on the caseload of a Community Matron.

9.3 Consent

During the consent/baseline visit potential participants will be given a further brief verbal explanation of the study. During this visit the participant will be given the opportunity to ask further questions about the study and decline the invitation to participate at this point, should they wish. If they agree to participate then the consent form will be completed at this time.

Consent process for participants is below:

The following procedure will be used to obtain informed consent agreement for participation:

- a. All eligible people who have agreed to be approached will be given verbal and written information about the study. Information will be provided in an appropriate form, for example a supported conversation around written material (e.g. patient information leaflets) to maximise understanding of what is being asked of them and to support them to make decisions.
- b. People will be informed that their care will not be affected in any way by their decision to take part or not.

People with mental capacity willing to take part in the trial will be invited to provide confirmation of informed consent to undergo baseline and follow-up assessments and data collection, and permission to access to patient's medical and social care records. If the person has capacity but cannot sign the consent form, this will be indicated on the consent form by the CI/RA completing the relevant box on the patients consent form and signing it. The original consent will be retained in the site file and checked by the CI. The CI/RA will confirm to PenCTU that written consent has been obtained and recorded on the CRF.

9.4 Randomisation

In order to avoid contamination of the control group, this study is designed as a feasibility pragmatic cluster RCT with randomisation at general practice level. It is anticipated that 50% of the general practices will be randomised to intervention and 50% will be randomised to control. Randomisation will take place once six PIC sites have been recruited to the trial and prior to consent and baseline outcome measures assessment. The exact details of the algorithm will be determined between the trial statistician and PenCTU programming team only.

9.5 Withdrawal Criteria

Each participant has the right to voluntarily withdraw from the study at any time, without recourse. Circumstances where this might occur, for instance, may be where he or she perceives an intolerable AE has occurred. In addition, the CI may discontinue a participant from the study at any time if the investigator considers it necessary due to:

- a. Ineligibility which may have been overlooked at screening
- b. An AE which requires discontinuation of the study intervention or results in inability to continue to comply with study procedures.

The judgement as to whether an AE is of sufficient severity to require the participant's intervention to be discontinued will be made by the CI in joint discussion with the participant, participant's clinician (e.g. General Practitioner/Community Matron). The reason for withdrawal will be recorded on a withdrawal form. For this feasibility study all participant drop outs will be included in the CONSORT diagram for pilot and feasibility trials.

Withdrawal of treatment from either the intervention or control group may occur due to intervention intolerance and reluctance/refusal of participating in the intervention. Number and reasons for withdrawals and any unanticipated/adverse events will be recorded and reported by the community matron or an RA using a withdrawal form. Participants who withdraw from treatment will be encouraged to remain in the trial for follow-up assessments. Wherever possible, study assessments will be undertaken at the appropriate sessions (three and six months) so as to minimise missing data.

10. TRIAL SCHEDULE

Table 2: Trial Schedule

	Pre-intervention		Intervention Period	Post-intervention	
	Participant identification	Baseline assessments prior to randomisation		3 months post randomisation	6 months post randomisation
Screen/eligibility	X				
PRISMA7	X				
Consent	X				
Collection of demographic information		X		X	X
Barthel Index of Activities of Daily Living		X		X	X
UCLA 3-Item Loneliness Scale		X		X	X
SF-36		X		X	X
Health Foundation LTC6 questionnaire		X		X	X
EQ-5D-5L		X		X	X
Number of falls		X		X	X
Number of medications		X		X	X
Number of hospital admissions		X		X	X
Number of readmissions		X		X	X
Total number of days spent in hospital		X		X	X
Interviews with participants				X	X
Interviews with carers				X	X
Interviews with clinicians					X

10.1 Trial Procedures by Visit

Once consent has been received, baseline assessment of outcome measures will be undertaken with the participants. All baseline assessments will be carried out in one session and at the same time as consent is obtained, then at three months (post-intervention) and six months after randomisation. They will be undertaken by the blinded assessor. All outcome measures and their corresponding assessments are detailed in Table 1.

10.2 Potential Primary and Secondary Outcome Measures

Standardised, validated clinician-rated and patient self-reported clinical outcomes will be measured in both groups at baseline and follow-up (three and six months). The blinded assessor will conduct assessments at these time points in the participant's home. All of the outcome measures listed in Table 1 will be undertaken at each of the follow-up study visits.

There will be two methods of data collection; from the primary care clinical record held on the general practice computer system and using patient reported outcome measures. Patient-reported and clinical record outcome measures will be collected at baseline, three and six months to minimise burden of multiple visits on frail patients and their carers. Answers to the questionnaires will be elucidated by the blinded assessors and answers recorded on the CRFs. All questionnaires have been validated for self-completion and the assessors will offer minimal assistance i.e. read out the questions as they appear on the document and hold up any visual analogue scales for the participant to point at the chosen point on the scale. The assessments will take approximately 60 minutes. They will be undertaken in the same order (as laid out in Table 1) for all participants to minimise the impact of confounding variables such as fatigue. Outcome measures have been informed by the literature and chosen in discussion with PPI representatives as important and relevant. Data will be collected on the feasibility of undertaking the outcome measures and the percentage of full outcome sets completed. As far as is possible, all outcome data will be collected for all participants, regardless as to whether or not they have adhered to the protocol. Reasons for non-adherence will be ascertained as far as practicable for the future study.

If a study visit to undertake assessments is missed, then the blinded assessor will book another appointment by telephone, as close as possible to the original scheduled date. The degree of compliance with the study schedule will be assessed.

10.3 Expected Duration of Participation

The expected duration of participation for all participants will be a maximum of seven months from consent. The intervention will begin within one month of consent and will consist of one initial assessment visit and followed by a maximum of six care-planning visits delivered

by the community matron over a 12 week period. Baseline assessments will be carried out at consent visit and follow-up assessments of outcome measures will occur at three and six months for all participants in the intervention and control arms.

10.4 End of Trial

The end of trial is the date of the last follow-up of the last participant. The following criteria will be used by the sponsor or TSC to prematurely stop the research:

- Unacceptable number of AEs
- A decision made by the TSC and TMG on the grounds of an unacceptably slow recruitment rate which does not seem retrievable within the study timeline.
- An evaluation via a fully powered RCT of a similar assessment and care planning intervention in moderately and severely frail people in primary care. Note that there are currently no similar trials registered with clinicaltrials.gov (last assessed 05/12/2017).

11. INTERVENTION PERIOD

11.1 Compliance

Reasons for non-compliance with the protocol will be provided. Clinician interviews as part of the embedded qualitative element at the end of the trial will help to ascertain possible reasons for non-compliance. If the delivery of the intervention and usual care is affected by logistical reasons within the community matron service these will be addressed by working with clinicians and their managers.

11.2 Unblinding

Trial assessors will be blind to group allocation at baseline and follow-up. Success of blinding will be recorded at these stages by the assessors on the CRF. If accidental unblinding occurred during this period the assessor will record details of the circumstances leading to unblinding. All GP practices will be reminded of the importance of not divulging any information to the

blinded assessor which may lead to unblinding prior to the first post-intervention assessment.

At the start of each encounter with participants and/or family members during the period of blinding, the assessor will kindly ask them not to discuss anything about their care and emphasise the importance of the assessor remaining blinded to group allocation.

12. EMBEDDED QUALITATIVE COMPONENT

This component of the trial explores the experiences of the study participants, their carers and the experiences of the clinicians who have delivered the intervention and GP practice staff who facilitated recruitment and eligibility screening. The aim is to generate recommendations and address unknowns including experiences of recruitment, retention, practical implementation and further refinement of the intervention and outcome measures for the design of the future RCT. This is to satisfy the trial objectives i-l (pp 16) In particular to:

1. To determine acceptability of the intervention to patients, carers and clinicians in primary care.
2. To assess barriers to delivery of the HAPPI intervention e.g. any operational difficulties within the community matron service.
3. To evaluate willingness to identify, recruit and randomise eligible patients, and willingness of patients to be recruited and randomised.
4. To determine acceptability of trial processes and collection of outcome measures to participants.

12.1 Methods

12.1.1 Sampling

A sample of participants will be invited for interview based on their characteristics and levels of severity of frailty (moderate and severe). Half the sample of participants and carers will be

interviewed at three months post-randomisation and half at six months. A maximum of six CMs who delivered the intervention will be approached for interview. As this is a feasibility study, this method allows identification of a targeted sample rapidly, and sampling for proportionality is not the main concern. Maximum sample numbers are described but if saturation is reached prior to these numbers, no further interviews will be conducted. The following purposive sample size is anticipated:

- A maximum of six study participants (four from the intervention arm, two from the control arm of the RCT).
- Four carers of study participants (two intervention arm, two control arm of the RCT).
- Two people who declined to participate at the outset, and two people who withdrew from the study before completion.
- A maximum of six community matrons who delivered the intervention.
- Four general practice administrators who implemented recruitment and eligibility screening procedures

It is understood that it might be ethically challenging to recruit to the qualitative study once a participant has declined the feasibility RCT. However, the importance of including these people is to explore their reasons for declining participation or withdrawal in order to use these data to inform the larger study protocol and maximise recruitment and retention.

12.1.2 Inclusion Criteria

Participants will be eligible for this part of the study provided they are:

- a. Able to use a range of communication methods including speech, gesture and/or writing.
- b. Able to recall involvement in the study or study processes with or without prompts or aids (e.g. study documentation) as required.
- c. Are able to provide written informed consent for a semi-structured interview related to their participation in the trial.

Carers will be eligible for the study provided they are:

- a. Aged ≥ 16 years.
- b. A family member/close friend of a participant in the intervention or control group.

- c. Able to provide written informed consent for a semi-structured interview related to their family member/close friend's participation in the trial.

Clinicians will be eligible for the study provided they are:

- a. A CM who delivered the intervention
- b. Willing to provide written informed consent for a semi-structured interview related to the feasibility of implementing the intervention and associated study processes

General Practice Administrators will be eligible for the study provided they:

- a. Willing to provide written informed consent for a semi-structured interview related to the feasibility of implementing the intervention and associated study processes

12.1.3 Exclusion Criteria

Participants will not be eligible for the study if any of the criteria below are met:

- a. Severely impaired communication and/or deficits in cognitive skills or hearing impacting on their ability to participate in an interview

Carers will not be eligible for the study if any of the criteria below are met:

- a. Aged <16 years
- b. Not a family member/close friend of a participant in either the intervention or control group
- c. Refuse to provide written informed consent for a semi-structured interview related to their family member/close friend's participation in the trial

Clinicians will not be eligible for the study if any of the criteria below are met:

- a. Refuse to provide written informed consent for a semi-structured interview related to the feasibility of implementing the intervention and associated study processes.

General Practice Administrators will not be eligible for the study if any of the criteria below are met:

- a. Refuse to provide written informed consent for a semi-structured interview related to the feasibility of implementing the intervention and associated study processes.

12.1.4 Data Collection

In-depth semi-structured interviews will be undertaken by the CI, which will last approximately 40 minutes. An interview protocol and topic guide will comprise questions relating to structure, process and outcome of the trial. The topic guide will not be exhaustive, with flexibility to offer space and the opportunity for participants to raise other issues which they might consider pertinent. All interviews will be audio recorded for their entire duration and transcribed verbatim by the CI or delegated staff. Interviews for patients and carers will be conducted at the patient's own home following an informal format, which it is envisaged will assist in creating a situation in which experiences will be openly shared, without participants fearing they are being too critical. Interviews for the community matrons will be conducted at their local work base or other CFT premises. All respondents will be assured of the anonymity of the data and that the interviews are intended to be non-judgemental.

12.1.5 Interviews

Community Matron Interviews

In particular, the CMs will be asked to describe, discuss and elaborate on:

- The situations they found interesting and challenging with regard to implementation of the HAPPI intervention with patients
- The situations they found interesting and challenging with regard to delivery of the HAPPI intervention e.g. any operational difficulties within the community matron service.

General Practice Administrator Interviews

In particular, the GP administrators will be asked to describe, discuss and elaborate on:

- The situations they found interesting and challenging with regard to the identification, screening and recruitment procedures.

Trial participant interviews

In particular, the participants will be asked to describe, discuss and elaborate on:

- The situations that they found interesting and challenging with regard to receiving the HAPPI intervention or usual care
- The situation that they found interesting and challenging with regard to the completion of each of the questionnaires
- The experience of participating in the trial

Decliner and Withdrawal Interviews

Up to two people who declined to participate at the outset will be interviewed and another two people will be interviewed if we have study participants who withdraw from the study. At the time they decline to participate in the study, or withdraw, they will be asked once only if they would be willing to share their reasons why they declined in a brief interview. They will be informed that the researchers would find any reasons they had for declining useful for developing this and future research. They will be clearly informed that this is entirely optional and they do not have to share their reasons. If they consent, they will be given an option to be interviewed alone or with their significant other. The aim is to explore their feelings about this feasibility study and reasons for declining or withdrawing in order to inform and optimise recruitment/retention for the remainder of the trial and subsequent main study. Data collection will occur within three days of declining or withdrawal. For the home visit, which is required as part of the qualitative interviews, the CI will comply with the NHS Trust lone working policy.

12.1.6 Data Analysis

Qualitative study results will be reported using the COREQ checklist for interviews and focus groups (24). Thematic analysis will be used to analyse the data. This method includes a strategy for identifying themes and subthemes (25). The transcripts of the interviews will be uploaded to the qualitative analysis program NVivo.

The first analysis step will involve familiarisation of the narratives and two researchers will independently read the transcripts. In the next step, two researchers will independently code the text by allocating the text fragments to codes. The codes will be formulated from the text fragments and will possibly be revised during the process of reading the transcripts. The two researchers will then discuss the results of the individual codes and try to reach consensus. After this, the codes will be reviewed and themes will be formulated.

12.1.7 Qualitative data presentation

Demographic data items will be presented using descriptive statistics. Meaningful text fragments will be determined, as will codes (sub-themes) and themes related to the trial objectives. Data extracts will be accompanied by narrative to elaborate why the extract is analytically interesting. All participants will be anonymised and pseudonyms used to demonstrate different participants' experiences. If any information is disclosed during the trial that could pose a risk of harm to the participant or others, the CI where appropriate, will report and act accordingly.

13. SAFETY REPORTING

Adverse events (AEs) may be non-serious or serious (see definitions below). Adverse events to be recorded in this study are:-

- All non-serious AEs considered to be related to the intervention
- All Serious Adverse Events (in all participants)

13.1 Definitions

An **adverse event (AE)** is defined as any unfavourable and unintended sign, symptom or disease that develops or worsens during the period of the trial, whether or not it is considered to be related to the trial intervention. Adverse events include unwanted side effects, injury or intercurrent illnesses.

An adverse event is classified as a **Serious Adverse Event (SAE)** if it:

- results in death
- is life threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- consists of a congenital anomaly or birth defect (not relevant in this population)
- or is considered by the investigator to be an important medical event

In this patient population of moderately and severely frail patients, acute illness resulting in hospitalisation, new medical problems and deterioration of existing medical problems are expected. For participants in this study who are moderately or severely frail, this will include SAEs relating to frailty syndromes such as admission to hospital for abrupt onset of falls, immobility, delirium caused by infection/sepsis, incontinence and iatrogenic side effects of medication.

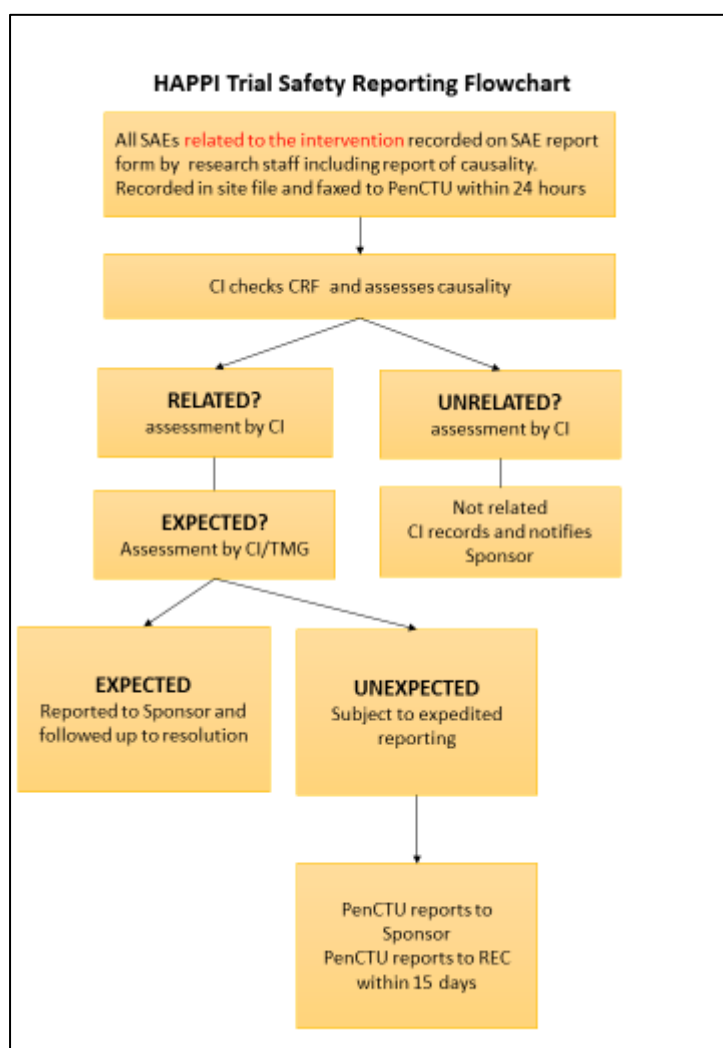
Deaths and falls are expected in this patient population at a higher prevalence than those seen in non-frail. Clegg et al (26) found that one-year adjusted Hazard Ratio (HR) for mortality

was 3.10 (95% CI 2.91–3.31) for moderate frailty and 4.52 (95% CI 4.16–4.91) for severe frailty. 30% of people aged 65 and over will fall at least once a year and for those aged 80 and over it is 50% (27). Increasing frailty is associated with higher prevalence of falls. In a recent systematic review frailty was significantly associated with higher risk of future falls (pooled HR = 1.24, 95% CI = 1.10–1.41, $P < .001$) (28). Numbers of deaths and falls are an outcome measure will be collected between the time of consent, three months and final follow up (six months).

13.2 Reporting adverse events

Reporting of adverse events in the HAPPI trial is summarised in Figure 3.

Figure 3: Flow chart of reporting AEs and SAEs



Adverse Events related to the intervention will be recorded in the CRF at three month and six month follow up visits by the blinded assessors (RAs) for all participants. For those participants at GP practices that have been allocated the intervention, Adverse Events will also be recorded in the CRF by the Community Matrons who are delivering the intervention.

13.3 Reporting Serious Adverse Events

Any adverse event that happens to a participant in the study that may be considered 'serious' according to the definition in section 13.1 will be reported by any member of staff working

on the study to PenCTU using the SAE report form. Once complete, the form will be faxed to PenCTU within 24 hours of the research staff becoming aware of the event and the original filed in the site file. PenCTU will advise the CI that an SAE has been reported, giving basic details and asking the CI for their opinion on relatedness. If either the reporting person or the CI considers that the SAE is possibly, probably or definitely related to the study treatment, then the CI and/or the TMG will be asked to determine whether or not the event is expected, based on the information given in section 13.1.

As described in section 13.1 high numbers of SAEs are expected within the study population. All SAEs will be reported annually to the Sponsor, Trial Steering Committee (TSC) Research Ethics Committee (REC) by way of routine annual progress reports in accordance with the trial monitoring plan. SAE listings will be reviewed at TMG meetings on an ongoing basis throughout the course of the data collection period.

For all participants, SAEs will be reported from the time they give consent to take part in the study until their 6 month follow up visit (or until they otherwise withdraw from the study). All SAEs will be followed up until the event has resolved or a final outcome has been reached.

13.4 Related and Unexpected SAEs – expedited reporting

SAEs which are considered possibly, probably or definitely related to the trial intervention and are considered unexpected by the CI and/or the TMG will trigger an expedited reporting procedure (in addition to the routine reporting described in section 13.2.2). The CI will contact the TSC to ask them to review the event and to consider if any corrective action needs to be taken for reasons of safety within the trial. Any related and unexpected SAEs will be reported

by the PenCTU to the Research Ethics Committee by email within 15 days of the local research team having become aware of the event.

14. DATA MANAGEMENT

14.1 Data Collection

The CRF will be a printed paper document. Data captured in the CRF for the sole purpose of this study will be considered source data. The CRF will consist of three sections:

- a. Intervention CRF: HAPPI intervention data: recorded by the community matron (intervention group only).
- b. Participant Baseline and Follow-up CRF: Participant related baseline, 3 month follow up, 6 month follow up; recorded by the CI/blinded RA (all participants)
- c. GP Practice Records CRF: GP Practice records; recorded by CST (all participants)

Completeness of outcome data will be maximised by the CI/RA, who will:

- a. Wherever possible, arrange another assessment session, should the pre-scheduled session be cancelled
- b. Ensure the participant will be referred to by their study participant number, not by name on all study-specific documents, other than (a) the signed consent and (b) the contact details form
- c. Ensure that a record of all participating patients is kept on a participant log, filed in the site file along with the originals of signed information consent forms
- d. The site files with the essential documentation will be stored at the Cornwall Foundation Trust Research nurse team and at the Kernow CCG CST office.
- e. Ensure each site retains a copy of each CRF that they send to PenCTU to ensure the CI can provide access to the source documents to a monitor, auditor, or regulatory agency.

Data will be recorded on the CRFs by the CI/RA and CMs. CRFs will be posted using pre-printed freepost labels to PenCTU for double data entry onto a password-protected database.

A customised database will be used for data entry. Data entry will be completed by a PenCTU Administrator. Double entered data will be compared for discrepancies. Discrepant data will be verified using the original paper data sheets. The CI will ensure that participants'

anonymity is maintained by ensuring each participant is allocated a study number which will be allocated during completion of the baseline CRF. Participant numbers will consist of 4 digits. The first two digits will relate to a number allocated to the GP practice from which the participant was identified and recruited. The next two numbers will be consecutively allocated by the CI as the baseline assessment visits are conducted.

Anonymised data will be securely stored for ten years after the completion of the trial in accordance with Plymouth University policy. The Sponsor will be responsible for archiving all trial data following submission of the end of study report.

14.2 Source Data

Data generated as a result of this trial will be available for inspection on request by the participating research team, Plymouth University representatives, the REC, local R&D Departments and Sponsor.

14.3 Data Confidentiality

Source data will only be accessed by the CMs delivering the intervention, the CI and RAs. Data will be collected and stored in accordance with the Data Protection Act 1998/General Data Protection Regulation 2018. All paper forms (including all original signed informed consent forms and copies of the CRFs) will be stored immediately after use in the Site File at each site separate from study data. After completion of the trial these will be accessible for the purposes of monitoring, auditing via the Sponsor who will be storing the anonymised data for ten years. The CI will be responsible for data analysis in collaboration with the trial

statisticians. All identifiable data will be destroyed as soon as the trial has ended and participants have been sent a summary of the results.

15. STATISTICAL CONSIDERATIONS

15.1 Sample Size

As a feasibility study, a formal sample size calculation based on considerations of power is not appropriate (29); this study is not powered to detect clinically meaningful between-group differences in a primary outcome. One of the aims of this study is to provide robust estimates of the likely rates of recruitment and follow-up, as well as provide estimates of the variability of the proposed primary and secondary outcomes to inform sample size calculations for the planned definitive trial. There is no consensus on the recommended number of participants required for a feasibility study, with published “rules of thumb” ranging from 20 to 70 or more participants, when the planned primary outcome is of a continuous nature. A recent paper recommended a feasibility study sample size should recruit 25 participants per allocated group, if the planned definitive trial will have a two-arm parallel group design, with 90% power and two-sided 5% significance level, to detect a “small” standardised effect size (30). Therefore, this feasibility study aims to recruit 60 participants in total.

Participants will be recruited from a minimum of six general practices in Cornwall, with a total practice population of 491,000. The planned recruitment period is six months and over this period, across the practices, it is anticipated that following initial screening (eFI), approximately 9000 (1500 per practice) potential participants will be identified and from these 540 (90 per practice) sampled for second screening (PRISMA7) and eligibility. Following second screening, it is estimated that around 30% of eligible participants will consent to

participate. Whilst the aim is to recruit 10 participants per cluster, once a cluster has between eight and 12 participants, the next cluster will be opened for recruitment.

Given the nature of the study, with measures being collected at baseline, three and six months, with time required for travelling between participant's homes and qualitative interviews, logistically it is estimated that the maximal recruitment rate is five to six participants per month.

A target sample size of 60 participants will allow the follow-up rate to be estimated to within $\pm 15\%$. The follow-up rate is estimated to be 70%, which would provide follow-up outcome data on a minimum of 42 participants across both allocated groups and three sites.

15.2 Statistical Analysis

A statistical analysis plan will be drafted by the CI with support from the trial statisticians and approved and signed off by the TSC. It is inappropriate to use feasibility study data to formally test treatment effects, therefore the statistical analyses will be of a descriptive nature (29). The plan will conform to guidance related to statistical analysis plans (31) and take into consideration the CONSORT updated guidelines for reporting feasibility and pilot trials (32) and also give consideration to the CONSORT Patient-Reported Outcome (PRO) extension: Health and Quality of Life Outcomes (33) and CONSORT Statement for Randomised Trials of Non-pharmacologic Treatments (34).

15.3 Analysis populations

All analyses and data summaries will be conducted on the intention-to-treat (ITT) population which is defined as all participants randomised regardless of non-compliance with the protocol or withdrawal from the study. Participants will be analysed according to the intervention they received.

15.4 Frequency of analysis

There is no planned interim analysis. Statistical analysis will be undertaken after the last participant's last visit and the database is locked. The statistical analysis plan will be developed and approved prior to database lock.

15.5 Outcome analysis

As a feasibility study, analysis will focus on descriptive statistics and confidence interval (CI) estimation rather than formal hypothesis testing (36). The aim of the analysis is to assess the feasibility of the intervention, the feasibility of a full definitive trial and summarise potential primary and secondary outcome measures.

Feasibility of a trial will include:

- CONSORT diagram
- timing of follow-up assessments (i.e. where they within a reasonable time frame)
- time it took to recruit sites/participants
- balance of baseline characteristics by allocation group
- number of researchers who became unblinded
- movement between practices (although potentially this may not be representative of the country).

Feasibility of the intervention will include:

- numbers who complied
- how much participants complied with intervention (i.e. one assessment and at least two care planning visits).

Potential primary/secondary outcomes assessment will include:

- summary statistics difference between baseline and follow-up visits
- completeness of data (missing completely and missing items).

16. DATA MONITORING

16.1 Data Monitoring Plan

Data will be monitored for quality and completeness by the PenCTU, using established verification, validation and checking processes. Two attempts will be made to gain any missing data, confirmed as not available, or when the trial is at analysis. The PenCTU/Sponsor reserve the right intermittently to conduct source data verification on a sample of participants. Source data verification will involve direct access to patient notes at the participating sites, and other relevant investigation reports.

16.2 Quality Assurance

The study will be conducted in accordance with the principles of Good Clinical Practice (GCP) in clinical trials, as applicable under UK regulations, the UK Policy Framework for Health and Social Care Research and through adherence to PenCTU Standard Operating Procedures (SOPs).

A Trial Monitoring plan will be developed and agreed by the Trial Management Group (TMG) and Trial Steering Committee (TSC). This will be informed by a Trial Risk Assessment which will consider the safety or physical or mental integrity of the trial participants and the scientific value of the research (including the potential risk associated with the implementation of the intervention and recruitment which can, if not monitored and mitigated, affect the integrity and smooth running of this cluster randomised feasibility

study). This monitoring plan will detail the timing and content of reports to monitor trial conduct and implementation and adherence with the Consolidated Standards of Reporting Trials (CONSORT) (33). This monitoring plan may also include site monitoring.

For a feasibility study of this nature and duration, a separate Data Monitoring Committee is not required. Rather, the TSC will adopt a safety monitoring role, with the constitution of a sub-committee to review safety issues where this becomes necessary.

16.3 Trial Steering Committee (TSC)

The TSC comprises a multi-disciplinary group of individuals who are independent to the TMG and include patient and public representatives. The TSC will meet once before the trial starts and at least six-monthly over the course of the trial. In addition, they will receive a quarterly update of the SAEs, and a telephone conference / additional face-to-face meeting will be instigated by the Chair or the CI should any issues need to be discussed.

The role of the TSC is to provide overall supervision of the HAPPI study on behalf of the study Sponsor and funder. In particular, the TSC will monitor the scientific integrity of the study including trial progress, adherence to the protocol and the consideration of new information. The TSC will also be responsible for reviewing accumulating safety data in order to monitor participant safety.

The TSC will provide advice through its independent Chairperson to the CI and the local trial management team on all aspects of the trial. TSC members will be constructively critical of the ongoing trial, but also supportive of its aims and methods. Minutes of the TSC will be sent to the Sponsor. The decisions made by this committee are independent of the sponsor and

investigators. There will be at least 40% independent representation (independent chair, independent scientist and three lay members).

The composition of the TSC for this trial is detailed in Table 3.

Table 3: Trial Steering Committee

Dr Iain Lang (Chair)*	Senior Lecturer in Public Health
Mr John Goddard*	Patient & Public Involvement Representative
Mrs Margaret Lappin*	Patient & Public Involvement Representative
Mrs Marie Prior*	Frailty Lead/Registered Nurse
Mrs Kerry Crowther*	Falls Lead/Registered Nurse
Dr Paul McEleney*	General Practitioner
Dr Frances Harrington*	Geriatrician
Helen Lyndon	Chief Investigator
Dr Chen Ji*	Independent Statistician

*Independent TSC Members

17. DIRECT ACCESS TO SOURCE DATA AND DOCUMENTS

The CI and the Plymouth University will permit trial-related monitoring, audits, REC review and regulatory inspections by providing direct access to source data and other documents.

18. ETHICS APPROVALS

The trial will not be initiated before the protocol, informed consent forms, Participation Information Sheets and other relevant documents (e.g. GP information letter, consent forms

and interview topic guides) have received approval from an NHS REC, and HRA approval is in place.

This trial protocol has been reviewed by the Trial Management Group, Trial Steering Committee and the Sponsor. Should a substantial protocol amendment be required, the changes in the protocol will not be instituted until the amendment and revised study documentation (if appropriate) have been reviewed and received approval from the REC and HRA. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Non-substantial amendments for logistical or administrative changes will be submitted to the HRA for approval before implementation.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Policy Framework for Health and Social Care Research. All correspondence with the REC will be retained in the Trial Master File and Investigator Site File.

An annual progress report will be submitted by the CI to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The CI will notify the REC of the end of the study. If the study is ended prematurely the CI will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

19. STATEMENTS OF INDEMNITY

Plymouth University indemnity scheme will meet the potential legal liability of the sponsor(s):

- for harm to participants arising from the management of the research
- for harm to participants arising from the design of the research
- arising from harm to participants in the conduct of the research

This is a Plymouth University research study. If an individual suffers negligent harm as a result of participating in the study, the Plymouth University indemnity scheme covers University employed. In the case of non-negligent harm, Plymouth University is unable to agree in advance to pay compensation, but the normal procedures for non-negligent harm will address this and an ex-gratia payment may be considered in the event of a claim.

20. PUBLICATION POLICY

The CONSORT Guidelines checklist will be reviewed prior to generating any publications for the trial to ensure they meet the standards required for submission to high quality peer reviewed journals etc. On completion of the trial, the data will be analysed and tabulated and a Final Study Report for the NIHR prepared by the CI. The full study report will be able to be accessed on the study web-site page. The participating investigators will have rights to publish the trial data; this will be undertaken only after discussion and in collaboration with the CI and after publication of the trial's main paper. There are no time limits or review requirements on the publications. The NIHR (the funding body) will be acknowledged within the publications. They do not have review and publication rights of the data from the trial.

All participants, who consent to receiving notifications, will be notified in writing of the outcome of the trial, either by provision of a lay summary of the results. If the trial is feasible,

dissemination of information will include the progression of this research. For example, future funding applications to undertake a randomised controlled trial to investigate the effectiveness of the HAPPI intervention.

The trial protocol will be submitted for publication in an Open Access Journal; it is anticipated that this will be available within one year of the recruitment start date for this trial. Findings based on the trial results will be published in peer-reviewed scientific journals, such as *Age and Ageing*, and in journals read by practicing clinicians in primary and community care, such as the *British Medical Journal* and *the International Journal of Older Peoples Nursing*. This will ensure dissemination to both academics and those responsible for service delivery in the NHS. Results will be presented at national and international conferences, such as the British Geriatrics Society Autumn and Spring Conferences and the Royal College of Nursing Older Peoples Conference. Additionally, older people will be informed through organisations such as AgeUK. If the trial is found to be feasible, the study-specific procedure guide and training materials will be implemented in the subsequent main trial.

21. STUDY ORGANISATIONAL STRUCTURE

Individuals and individual organisations:

Chief Investigator

As defined by the NHS Research Governance Framework, the Chief Investigator is responsible for the design, management and reporting of this study, the whole research programme and its constituent parts. The CI will also be conducting qualitative interviews.

Sponsor

The Sponsor is responsible for trial initiation management and financing of the trial. These responsibilities are delegated to the PenCTU as detailed in the trial contract.

Peninsula Clinical Trials Unit (PenCTU)

The PenCTU will support set-up and monitoring of study conduct to PenCTU SOPs and MRC GCP standards including randomisation design and implementation, registration design and implementation, database development and provision, assisting the CI with protocol development, CRF design, study design, monitoring schedule and statistical analysis and reporting. The PenCTU will be responsible for the database administrative functions, data management, safety reporting, and supporting the CI with statistical analyses.

South West Peninsula Clinical Research Network (SWCRN) (Primary Care Clinical Speciality)

The SWCRN will support main REC and Research and Development submissions, and site set-up and on-going management including non-clinical training, monitoring reports and promotion of the study. The SWCRN will be responsible for day-to-day management of the study, supporting the CI with R&D submissions, liaison with local collaborators, management and overall supervision of the performance and conduct of the research team, source data verification (where required) and promotion of the programme.

Research Assistants (RAs)

Study-specific RAs (specifically Cornwall Foundation Trust Research Nurses) will have responsibility for screening, consenting patients, conducting baseline and follow-up assessments.

Staff delivering the intervention

Site staff are responsible for conducting the study in accordance with the trial protocol, the HAPPI conversation guide, personalised support plan template and assessment pack.

22. FINANCES

The trial is funded through an NIHR Clinical Doctoral Research Fellowship award. Ref no: ICA-CDRF-2016-02-018.

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Appendix 8: Site Eligibility Questionnaire

General Practice Participant Identification Site Eligibility Form

To participate in the HAPPI research study as a Participant Identification Site the Practice will need to agree to complete the following actions:

1. Run the electronic frailty index (eFI) database search to identify all moderately and severely frail patients aged 65 years and above.
2. Send an anonymised list of these patients to the Peninsula Clinical Trials Unit to enable sampling to be carried out.
3. Apply additional eligibility criteria to patients sampled:
 - Confirm the patient is able to give informed consent or consent can be obtained from a consultee
 - Confirm the patient lives in own home/supported living accommodation
 - Confirm the patient is not in receipt of palliative care, on gold standards framework register or where clinician feels they have limited life expectancy
4. Send a recruitment letter to a maximum of 90 potential participants (sampled by the CTU) and receive replies. If 90 is not reached in the initial invitation, CTU will repeat sampling until 90 is reached.
5. Follow-up recruitment letter with one telephone call if reply not received within fourteen days
6. Send details of 10 potential participants to the Chief Investigator(CI)
7. Complete email proforma report on 3 and 6 month outcome measures from general practice records system

A total of £ 193.76 will be paid to the practice in research and service support costs.

Please confirm the following criteria:

The practice uses the electronic frailty index (eFI) to identify their moderately and severely frail population	<input type="checkbox"/>
The practice are willing to fulfil the requirements of the study above relating to screening and recruitment of participants	<input type="checkbox"/>
The practice has at least one Community Matron attached to the practice who is willing to deliver the HAPPI intervention**	<input type="checkbox"/>

** NB this will be confirmed by the CI with Cornwall Foundation NHS Trust (Community Matron employer)

General Practice Name:

Signed By:

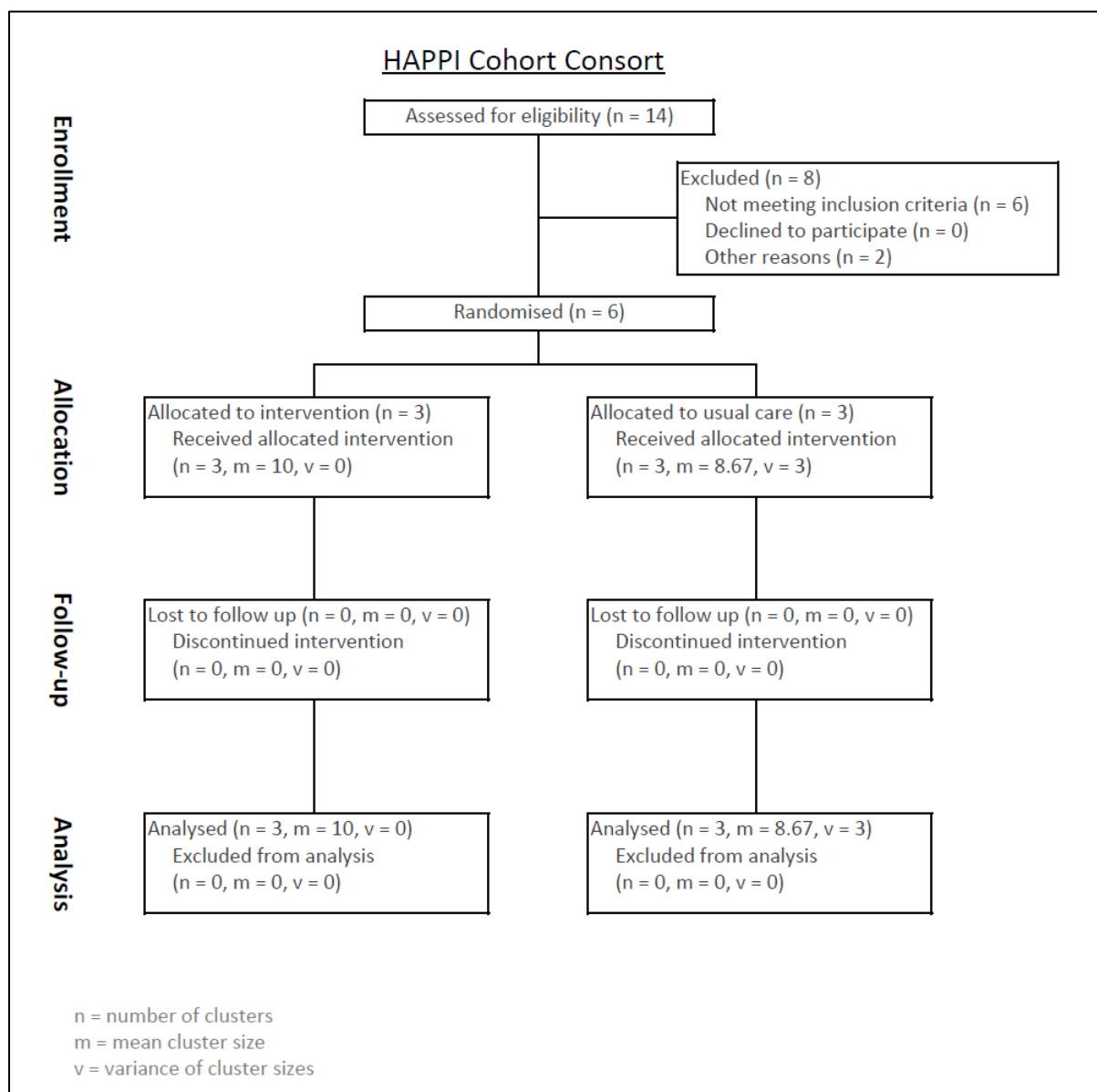
Signature:

Role:

Contact details: Phone Number:

Email:

Appendix 9: HAPPI Cluster Cohort Flow Chart



Appendix 10: HAPPI Invitation to Participate

General Practice Headed Notepaper

<<Date>>
<<Name of potential participant>>
<<Address>>
<<Town/City, County, Postcode>>

Re: The HAPPI Study, Lead Researcher: Helen Lyndon

Dear <<insert name>>:

I am writing to let you know about an opportunity to participate in a research study to test a new care plan for older people, to see if it is practical and achievable. This study is being conducted by myself, Helen Lyndon at the School of Nursing and Midwifery, University of Plymouth. Our research aims to explore how older people can be best supported at home and how community nurses could work to provide individualised support. We want to explore if we can measure improvements for older people enabling them to be as independent as possible, improve wellbeing, prevent falls and reduce the need for unplanned hospital care.

You have been identified as being a suitable candidate to participate in this research study by your General Practitioner Dr <<insert Dr's name>>. If you are interested in taking part in the study, please complete the questionnaire and the confirmation of participation sheet that is on the back of this letter and return it to the surgery in the stamped-addressed envelope provided. This will enable us to check if you are suitable to take part in the study. If you return the questionnaire and are suitable to join the study, a member of the research team will contact you by telephone to arrange to visit you at home to explain the study further and gain your written consent if you still wish to participate.

If we do not hear from you within 14 days, someone from the surgery will contact you by telephone. If you do not want to be contacted, please let us know by calling the surgery on <<insert surgery number>> and requesting that we make no further contact regarding this research. Agreement to be contacted or a request for more information does not mean that you will then have to participate in the study.

If you would like additional information about this study, please call me, Helen Lyndon, on 07919891065. Thank you again for considering this research opportunity.

Yours sincerely



Helen Lyndon (Mrs)
NIHR Clinical Doctoral Research Fellow/Nurse Consultant, Plymouth University

QUESTIONNAIRE

Please tick any that apply to you currently:

PRISMA-7 Questions	Please tick
Are you aged more than 85 years?	
Are you male?	
In general do you have any health problems that require you to limit your activities?	
Do you need someone to help you on a regular basis?	
In general do you have any health problems that require you to stay at home?	
In case of need can you count on someone close to you?	
Do you regularly use a stick, walker or wheelchair to get about?	

	Please tick
I am interested in participating in this research study if I am eligible and would like a member of the research team to contact me. I am happy for my name and phone number to be shared with the research team.	
I am not interested in participating in this research study and want no further contact from the research team	
Name (please print)	
Signature	
Date	

Appendix 11: HAPPI Participant Information Sheets



The HAPPI Study: Developing and testing an assessment and care plan to support older people who live with frailty at home.

Participant Information Sheet

We would like to invite you to take part in our research study

Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if anything is not clear, or if you would like more information. You can contact us on the number at the end of this sheet.

Why is this research important?

We know that as we get older some people face challenges of multiple health problems which can lead to loss of resilience, independence and may become more frail. From the age of 80, between a quarter and a half of people will show some of the signs of frailty so it is important that we understand the causes and how best to manage the condition for the future. Like many long-term conditions frailty cannot be cured and as we are living longer, we need to understand how to empower people to live well into older age.

Our research aims to explore how frail people can be best supported at home and how community nurses need to work to provide individualised support. We want to explore if we can measure outcomes for patients such as being able to live at home, improve wellbeing, prevent falls and reduce the need for hospital care.

Who is funding and organising the research?

This study is being funded by the National Institute of Health Research and carried out by Helen Lyndon who is a Community Nurse and Research Fellow based at Plymouth University. Older people have been involved in designing the study so far including advising on the elements of the care and support that are important. Older people and carers will be part of the study steering and management groups that will oversee the research.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the XXX Ethics Committee.

What's Involved?

This study aims to find out if it is possible to develop an assessment and care plan based on the individual needs of frail older people that can be used by nurses in partnership with patients and their carers. We will undertake a small study to test this new assessment and care plan to see if it is practical and achievable. In this part of the study, there will be a group of people who receive the new assessment and care plan and a group who will receive care as usual. In the final part of this study we will



talk to frail patients, carers and nurses to explore their experiences of participating in the research study.

What would taking part involve?

Your General Practice have agreed to take part in this study and this means that patients of the practice will be randomly allocated to one of two groups: either to receive the new assessment and care plan intervention or to receive usual primary care. Your general practice will be allocated at random (by chance - like tossing a coin). Then as a patient of that practice, you will continue to receive the same treatment throughout the study. Whether you are allocated to the intervention or the usual care group, the study involves regular assessments over about six months with up three study visits at your home. If you decide to take part, your GP will be informed.

We are aiming for 60 people with moderate or severe frailty to take part in the study. Half of those recruited will take part in the HAPPI assessment and care planning process and the other half will receive their usual primary care.

The HAPPI assessment and care planning process will involve up to six visits from a community nurse to you at home to work in partnership with you to assess your needs and develop a care plan to help address them. Usual care means just that "care as usual" from your GP, nurse or any other member of primary or community health services such as visits to your GP, medication, vaccinations etc.

All participants in the study will receive three study visits from the research team, one to gain your consent to take part and ask you questions to get baseline outcome measures. The other two visits will be at three and six months to follow-up on the outcome measures. This will involve you answering some questionnaires relating your health and well-being. It is expected that these study visits will last up to an hour each time.

Do I have to take part?

No. Participation is entirely voluntary. It is up to you to decide whether or not to take part in the study. If you decide not to take part, this will not affect the care and treatment you receive from your general practice. You do not have to take part and you do not have to give a reason for this. However, if you are willing to share your reasons with the researcher, this will be useful to us when we design other studies in the future.

If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. Even if you do decide to take part you can change your mind and be removed from the study at any time.

What are the possible benefits of taking part?

If you take part and are allocated to the intervention group, then you will receive visits and support from a nurse which may be in addition to your normal care and support. We cannot guarantee any specific benefits from this, but participating in research does



deliver wider benefits to society and others with a similar condition and will help us to determine how best to support people in the future.

What are the possible disadvantages and risks of taking part?

Participating in the research is not anticipated to cause you any disadvantages or discomfort. You will be asked to give some of your time as described earlier and this may be inconvenient to you.

What will happen to the results of the research study?

We hope the results will help us to design a large scale trial that will test further the HAPPI intervention. The results of this part of the research study will be written up and will form the basis of the lead researcher's PhD thesis.

Parts of the study will also be written up for the purposes of publishing the findings in health related journals and papers, or presentation at conferences. An additional short report of the research findings will be provided to the NHS Trust for distribution to participants. However, your data will always remain anonymous and your name will not appear on any of the results or write up. Results will also be made available on our website: <https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi>

How will my information be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential. The research team will publish the results of the study and other research documents, but you will not be able to be identified or identifiable in any reports or publications. Any data collected about you will be stored online in a form protected by passwords and other relevant security processes and technologies. Data collected may be shared in an anonymised form to allow reuse by the research team and other third parties. These anonymised data will not allow any individuals to be identified or identifiable.

How will my personal information be used?

Plymouth University is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Plymouth University will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.



Cornwall Partnership NHS Foundation Trust will keep your name, NHS number and contact details confidential and will not pass this information to Plymouth University. Cornwall Partnership NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Plymouth University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Plymouth University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Cornwall Partnership NHS Foundation Trust will keep identifiable information about you from this study for 5 years after the study has finished.

You can find out more about how we use your information by contacting the Lead Researcher whose contact details are at the end of this leaflet.

Who can I speak to if I want more information?

If you have any questions about this research please contact:

Helen Lyndon, Lead Researcher/Nurse Consultant

Tel: 07919 891065

Email: helen.lyndon@plymouth.ac.uk



The HAPPI Study: Developing and testing an assessment and care plan to support older people who live with frailty at home.

Participant Information Sheet – Participant Qualitative Interviews

We would like you to take part in the interview section of the HAPPI study. Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if anything is not clear, or if you would like more information. You can contact us on the number at the end of this sheet.

Why have I been invited to take part?

You have been invited to take part in this part of the study because you have participated in the feasibility trial of the HAPPI intervention.

What is the aim of this part of the study?

The aim of this part of the study is to explore your views on your experience of being involved in the HAPPI study so far. This information will help to improve the design of a larger scale study in the future.

What would I have to do?

If you decide to take part in the study, you will have a face-to-face interview with a researcher, during which you will be asked about your experiences of being part of the feasibility trial. The interview is expected to last approximately 20-40 minutes and will take place at a time and place convenient to you. This may be in your home or can be arranged in another location.

Do I have to take part?

No. It is entirely up to you whether or not to take part or later withdraw. If you decide not to take part, your care will not be affected in any way. If you agree to be interviewed, you can withdraw at any time during or after the interview. If you decide to withdraw at any stage, information collected during the interview may still be used unless you ask for it not to be.

If you decide to take part you will be asked to sign a consent form. You will be given a copy of the signed consent form and a copy of this information sheet for your own records.

What are the potential risks or benefits of taking part?

Risks

The interview will take a short time out of your day, but every effort will be made to minimise inconvenience and to ensure your comfort in the interview process. Many people value the opportunity to talk about their experiences, but it will be possible to take a break or stop at any point during the interview.

If the interview brings up issues you wish to discuss further, you can be referred to more expert sources of support if required.



Benefits

Although this research is unlikely to be of direct benefit to you, it will give you the opportunity to talk about your experiences and express your opinion on a variety of subjects to an interested, non-judgemental listener who is interested in your views.

What will happen to the results of the research study?

We hope the results will help us to design a large scale trial that will test further the HAPPI intervention. The results of this part of the research study will be written up and will form the basis of the lead researcher's PhD thesis.

Parts of the study will also be written up for the purposes of publishing the findings in health related journals and papers, or presentation at conferences. An additional short report of the research findings will be provided to the NHS Trust for distribution to participants. However, your data will always remain anonymous and your name will not appear on any of the results or write up. Results will also be made available on our website: <https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi>

Your rights

Your participation in this part of the study is entirely voluntary. You may withdraw at any time without giving a reason for withdrawal or without it affecting your current or future health care treatment in any way.

Will my records be confidential?

With your consent, the interview will be recorded and transcribed. Transcription will be undertaken by the Chief Investigator. All information collected about you during the course of this research will be kept strictly anonymised. All published information including any direct quotations from our interview will be anonymised and reference to services and people deleted.

All the information that we collect about you during the course of the research will be kept strictly confidential. The research team will publish the results of the study and other research documents, but you will not be able to be identified or identifiable in any reports or publications. Any data collected about you will be stored online in a form protected by passwords and other relevant security processes and technologies. Data collected may be shared in an anonymised form to allow reuse by the research team and other third parties. This anonymised data will not allow any individuals to be identified or identifiable.

How will my personal information be used?

Plymouth University is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Plymouth University will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that



we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Cornwall Partnership NHS Foundation Trust will keep your name, NHS number and contact details confidential and will not pass this information to Plymouth University. Cornwall Partnership NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Plymouth University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Plymouth University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Cornwall Partnership NHS Foundation Trust will keep identifiable information about you from this study for 5 years after the study has finished.

You can find out more about how we use your information by contacting the Chief Investigator whose contact details are at the end of this leaflet.

What if I have any further questions or require further information?

If you have any questions about this research please contact:

Helen Lyndon, Chief Investigator/Nurse Consultant

Tel: 07919 891065

Email: helen.lyndon@plymouth.ac.uk



The HAPPI Study: Developing and testing an assessment and care plan to support older people who live with frailty at home.

Participant Information Sheet – Clinician/Practice Administrator Qualitative Interviews

We would like you to take part in the interview section of the HAPPI study. Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if anything is not clear, or if you would like more information. You can contact us on the number at the end of this sheet.

Why have I been invited to take part?

You have been invited to take part in this part of the study because of you have participated in the delivery of the feasibility trial of the HAPPI intervention either as a clinician delivering the intervention or in identifying and screening patients for the trial.

What is the aim of this part of the study?

The aim of this part of the study is to explore your views and experience of being involved in the HAPPI study so far. This information will help to improve the design of a larger scale study in the future.

What would I have to do?

If you decide to take part in the study, you will have a face-to-face interview with a researcher, during which you will be asked about your experiences of being part of the feasibility trial. The interview is expected to last approximately 20-40 minutes and will take place at a time and place convenient to you.

Do I have to take part?

No. It is entirely up to you whether or not to take part or later withdraw. If you decide not to take part, there are no consequences. If you agree to be interviewed, you can withdraw at any time during or after the interview. If you decide to withdraw at any stage, information collected during the interview may still be used unless you ask for it not to be.

If you decide to take part you will be asked to sign a consent form. You will be given a copy of the signed consent form and a copy of this information sheet for your own records.

Will my records be confidential?

With your consent, the interview will be recorded and written up by the Lead Researcher. All information collected about you during the course of this research will be kept strictly anonymised. All published information including any direct quotations from our interview will be anonymised and reference to services and people deleted.

All the information that we collect about you during the course of the research will be kept strictly confidential. The research team will publish the results of the study and other research documents, but you will not be able to be identified or identifiable in



any reports or publications. Any data collected about you will be stored online in a form protected by passwords and other relevant security processes and technologies. Data collected may be shared in an anonymised form to allow reuse by the research team and other third parties. This anonymised data will not allow any individuals to be identified or identifiable.

What are the potential risks or benefits of taking part?

Risks

The interview will take a short time out of your day, but every effort will be made to minimise inconvenience and to ensure your comfort in the interview process. Many people value the opportunity to talk about their experiences, but it will be possible to take a break or stop at any point during the interview.

If the interview brings up issues you wish to discuss further, you can be referred to more expert sources of support if required.

Benefits

Although this research is unlikely to be of direct benefit to you, it will give you the opportunity to talk about your experiences and express your opinion on a variety of subjects to an interested, non-judgemental listener who is interested in your views.

What will happen to the results of the research study?

We hope the results will help us to design a large scale trial that will test further the HAPPI intervention. The results of this part of the research study will be written up and will form the basis of the lead researcher's PhD thesis.

Parts of the study will also be written up for the purposes of publishing the findings in health related journals and papers, or presentation at conferences. An additional short report of the research findings will be provided to the NHS Trust for distribution to participants. However, your data will always remain anonymous and your name will not appear on any of the results or write up. Results will also be made available on our website: <https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi>

Your rights

Your participation in this part of the study is voluntary. You may withdraw at any time without giving a reason for withdrawal or without it affecting your current or future health care treatment in any way.

What if I have any further questions or require further information?

If you have any questions about this research please contact:

Helen Lyndon, Chief Investigator/Lead Researcher

Tel: 07919 891065

Email: helen.lyndon@plymouth.ac.uk



The HAPPI Study: Developing and testing an assessment and care plan to support older people who live with frailty at home.

Participant Information Sheet – Carer Qualitative Interviews

We would like you to take part in the interview section of the HAPPI study. Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if anything is not clear, or if you would like more information. You can contact us on the number at the end of this sheet.

Why have I been invited to take part?

You have been invited to take part in this part of the study because you are the carer of a person who has participated in the feasibility trial of the HAPPI intervention.

What is the aim of this part of the study?

The aim of this part of the study is to explore your views on your experience of being involved in the HAPPI study so far. This information will help to improve the design of a larger scale study in the future.

What would I have to do?

If you decide to take part in the study, you will have a face-to-face interview with a researcher, during which you will be asked about your experiences of being part of the feasibility trial. The interview is expected to last approximately 20-40 minutes and will take place at a time and place convenient to you.

Do I have to take part?

No. It is entirely up to you whether or not to take part or later withdraw. If you agree to be interviewed, you can withdraw at any time during or after the interview. If you decide to withdraw at any stage, information collected during the interview may still be used unless you ask for it not to be.

If you decide to take part you will be asked to sign a consent form. You will be given a copy of the signed consent form and a copy of this information sheet for your own records.

What are the potential risks or benefits of taking part?

Risks

The interview will take a short time out of your day, but every effort will be made to minimise inconvenience and to ensure your comfort in the interview process. Many people value the opportunity to talk about their experiences, but it will be possible to take a break or stop at any point during the interview.

If the interview brings up issues you wish to discuss further, you can be referred to more expert sources of support if required.



Benefits

Although this research is unlikely to be of direct benefit to you, it will give you the opportunity to talk about your experiences and express your opinion on a variety of subjects to an interested, non-judgemental listener who is interested in your views.

What will happen to the results of the research study?

We hope the results will help us to design a large scale trial that will test further the HAPPI intervention. The results of this part of the research study will be written up and will form the basis of the lead researcher's PhD thesis.

Parts of the study will also be written up for the purposes of publishing the findings in health related journals and papers, or presentation at conferences. An additional short report of the research findings will be provided to the NHS Trust for distribution to participants. However, your data will always remain anonymous and your name will not appear on any of the results or write up. Results will also be made available on our website: <https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi>

Your rights

Your participation in this part of the study is entirely voluntary. You may withdraw at any time without giving a reason for withdrawal or without it affecting your current or future health care treatment in any way.

Will my records be confidential?

With your consent, the interview will be recorded and transcribed. Transcription will be undertaken by the Chief Investigator. All information collected about you during the course of this research will be kept strictly anonymised. All published information including any direct quotations from our interview will be anonymised and reference to services and people deleted.

All the information that we collect about you during the course of the research will be kept strictly confidential. The research team will publish the results of the study and other research documents, but you will not be able to be identified or identifiable in any reports or publications. Any data collected about you will be stored online in a form protected by passwords and other relevant security processes and technologies. Data collected may be shared in an anonymised form to allow reuse by the research team and other third parties. This anonymised data will not allow any individuals to be identified or identifiable.

How will my personal information be used?

Plymouth University is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Plymouth University will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that HAPPI PIS carers interview V1 09/07/2018/IRAS 229210



we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Cornwall Partnership NHS Foundation Trust will keep your name, NHS number and contact details confidential and will not pass this information to Plymouth University. Cornwall Partnership NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Plymouth University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Plymouth University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Cornwall Partnership NHS Foundation Trust will keep identifiable information about you from this study for 5 years after the study has finished.

You can find out more about how we use your information by contacting the Chief Investigator whose contact details are at the end of this leaflet.

What if I have any further questions or require further information?

If you have any questions about this research please contact:

Helen Lyndon, Chief Investigator/Nurse Consultant

Tel: 07919 891065

Email: helen.lyndon@plymouth.ac.uk



The HAPPI Study: Developing and testing an assessment and care plan to support older people who live with frailty at home.

Participant Information Sheet: Recovered Capacity

You are being invited to consider continuing to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask me if there is anything that is not clear or if you would like more information. Thank you for reading this.

Why am I already in this study?

During your recent illness you were unable to give consent for entry into a study, we therefore asked your nearest relative or welfare attorney or guardian who gave consent on your behalf to enter this study. This is permissible under the Mental Capacity Act 2005.

Why is this research important?

We know that as we get older some people face challenges of multiple health problems which can lead to loss of resilience, independence and may become more frail. From the age of 80, between a quarter and a half of people will show some of the signs of frailty so it is important that we understand the causes and how best to manage the condition for the future. Like many long-term conditions frailty cannot be cured and as we are living longer, we need to understand how to empower people to live well into older age.

Our research aims to explore how frail people can be best supported at home and how community nurses need to work to provide individualised support. We want to explore if we can measure outcomes for patients such as being able to live at home, improve wellbeing, prevent falls and reduce the need for hospital care.

Who is funding and organising the research?

This study is being funded by the National Institute of Health Research and carried out by Helen Lyndon who is a Community Nurse and Research Fellow based at Plymouth University. Older people have been involved in designing the study so far including advising on the elements of the care and support that are important. Older people and carers will be part of the study steering and management groups that will oversee the research.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the XXX Ethics Committee.



What's Involved?

This study aims to find out if it is possible to develop an assessment and care plan based on the individual needs of frail older people that can be used by nurses in partnership with patients and their carers. We will undertake a small study to test this new assessment and care plan to see if it is practical and achievable. In this part of the study, there will be a group of people who receive the new assessment and care plan and a group who will receive care as usual. In the final part of this study we will talk to frail patients, carers and nurses to explore their experiences of participating in the research study.

What does continuing to take part involve?

Your General Practice have agreed to take part in this study and this means that patients of the practice will be randomly allocated to one of two groups: either to receive the new assessment and care plan intervention or to receive usual primary care. Your general practice will be allocated at random (by chance - like tossing a coin). Then as a patient of that practice, you will continue to receive the same treatment throughout the study. Whether you are allocated to the intervention or the usual care group, the study involves regular assessments over about six months with up three study visits at your home. If you decide to take part, your GP will be informed.

We are aiming for 60 people with moderate or severe frailty to take part in the study. Half of those recruited will take part in the HAPPI assessment and care planning process and the other half will receive their usual primary care.

The HAPPI assessment and care planning process will involve up to six visits from a community nurse to you at home to work in partnership with you to assess your needs and develop a care plan to help address them. Usual care means just that "care as usual" from your GP, nurse or any other member of primary or community health services such as visits to your GP, medication, vaccinations etc.

All participants in the study will receive three study visits from the research team, one to gain your consent to take part and ask you questions to get baseline outcome measures. The other two visits will be at three and six months to follow-up on the outcome measures. This will involve you answering some questionnaires relating your health and well-being. It is expected that these study visits will last up to an hour each time.

Do I have to continue taking part?

No. Participation is entirely voluntary. It is up to you to decide whether or not to take part in the study. If you decide not to take part, this will not affect the care and treatment you receive from your general practice. You do not have to take part and you do not have to give a reason for this. However, if you are willing to share your reasons with the researcher, this will be useful to us when we design other studies in the future.

If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. Even if you do decide to take part you can change your mind and be removed from the study at any time.



What are the possible benefits of continuing to take part?

If you continue taking part and are allocated to the intervention group, then you will receive visits and support from a nurse which may be in addition to your normal care and support. We cannot guarantee any specific benefits from this, but participating in research does deliver wider benefits to society and others with a similar condition and will help us to determine how best to support people in the future.

What are the possible disadvantages and risks of taking part?

Participating in the research is not anticipated to cause you any disadvantages or discomfort. You will be asked to give some of your time as described earlier and this may be inconvenient to you.

What will happen to the results of the research study?

We hope the results will help us to design a large scale trial that will test further the HAPPI intervention. The results of this part of the research study will be written up and will form the basis of the lead researcher's PhD thesis.

Parts of the study will also be written up for the purposes of publishing the findings in health related journals and papers, or presentation at conferences. An additional short report of the research findings will be provided to the NHS Trust for distribution to participants. However, your data will always remain anonymous and your name will not appear on any of the results or write up. Results will also be made available on our website: <https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi>

How will my information be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential. The research team will publish the results of the study and other research documents, but you will not be able to be identified or identifiable in any reports or publications. Any data collected about you will be stored online in a form protected by passwords and other relevant security processes and technologies. Data collected may be shared in an anonymised form to allow reuse by the research team and other third parties. These anonymised data will not allow any individuals to be identified or identifiable.

How will my personal information be used?

Plymouth University is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Plymouth University will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that



we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Cornwall Partnership NHS Foundation Trust will keep your name, NHS number and contact details confidential and will not pass this information to Plymouth University. Cornwall Partnership NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Plymouth University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Plymouth University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Cornwall Partnership NHS Foundation Trust will keep identifiable information about you from this study for 5 years after the study has finished.

You can find out more about how we use your information by contacting the Lead Researcher whose contact details are at the end of this leaflet.

Who can I speak to if I want more information?

If you have any questions about this research please contact:

Helen Lyndon, Lead Researcher/Nurse Consultant

Tel: 07919 891065

Email: helen.lyndon@plymouth.ac.uk

Appendix 12: HAPPI Consent Forms



The Holistic Assessment and care Planning in Partnership Intervention Study

Consent Form

Version 1: 17/07/2018

Site Number:

Study Number:

Name of Researcher:

Please initial
each box

1. I confirm that I have read and understand the information sheet
Version: _____ dated _____ and I have had the
opportunity to consider the information, ask questions and have had these answered
satisfactorily ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any
time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of any of my medical notes and information
collected about me during the study may be looked at by responsible individuals from
my local NHS Trust, the study organisers and regulatory authorities where it is relevant
to my taking part in this research. I give permission for these individuals to have
access to my records ☐
4. I consent to the storage of data, including personal information, for the purposes of
this study on a password protected and encrypted University of Plymouth computer.
I understand that any information that could identify me will be kept strictly confidential
and that no personal information will be included in the study report or other
publication. ☐
5. I agree to my GP being informed of my participation in the study ☐
6. I agree to take part in the above study ☐

Name of patient

Date

Signature

Name of person taking consent

Date

Signature

When completed: 1 for patient, 1 for medical record (original), 1 for researcher site file



The Holistic Assessment and care Planning in Partnership Intervention Study

Consent Form – Clinician/Practice Administrator Interviews

Version 1: 06/06/2018

Site Number:

Study Number:

Name of Researcher: Helen Lyndon

Please initial
each box

1. I confirm that I have read and understand the information sheet
Version:..... dated and I have had the opportunity to consider the information,
ask questions and have had these answered satisfactorily ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any
time without giving any reason, without my legal rights being affected. ☐
3. I understand that information collected about me during the study may be looked at
by responsible individuals from the study organisers and regulatory authorities where
it is relevant to my taking part in this research. I give permission for these individuals
to have access to my information. ☐
4. I consent to the storage of data, including personal information, for the purposes of
this study on a password protected and encrypted University of Plymouth computer.
I understand that any information that could identify me will be kept strictly
confidential and that no personal information will be included in the study report or
other publication. ☐
5. I agree to take part in the above study ☐

Name of participant

Date

Signature

Name of person taking consent

Date

Signature

When completed: 1 for participant and 1 for researcher site file (original)



Participant Study Number:

CONSENT FORM – PARTICIPANTS (Interview section of study)

Title of Project: HAPPI Study

Name of Researcher: Helen Lyndon

Version 1: 06/06/2018

Please initial box

1. I understand that I have taken part in the main part of the study and consented separately for my participation. I understand that some participants will be invited to take part in an interview and because I have been invited that I need to sign a separate consent for the interview aspect of the study
2. I confirm that I have read and understand the information sheet dated xxxxx (version xx) for the above study that includes details about the interview section of the research study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
4. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from University of Plymouth, Cornwall Foundation NHS Trust or the regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
5. I agree that information collected about me during the course of the study will be stored confidentially and securely on University of Plymouth premises in accordance with the Data Protection Act 1998.
6. I understand that the interview will be audio-recorded and then written out word-for-word as soon as possible. I understand that the information I provide will be anonymised to protect my confidentiality and that extracts from the interviews may be used with my consent in study reports, conferences or publications. I understand that I will not be able to be identified in any of the write up or publication.
7. I agree to take part in the above aspect of the study.

Name of Participant

Date

Signature

Name of Person taking
Consent

Date

Signature

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

HAPPI Participant interview consent form V1 06/06/2018/IRAS No: 229210



CONSENT FORM – CARERS (Interview section of study)

Title of Project: HAPPI Study

Name of Researcher: Helen Lyndon

Version 1 06/06/2018

Please initial each box

1. I confirm that I have read and understand the information sheet
Version: _____ dated _____ for the I have had the
opportunity to consider the information, ask questions and have had these
answered satisfactorily ☐
2. I understand that my participation is voluntary and that I am free to withdraw at
any time without giving any reason, without my medical care or legal rights being
affected. ☐
3. I consent to the storage of data, including personal information, for the purposes
of this study on a password protected and encrypted Plymouth University
computer. I understand that any information that could identify me will be kept
strictly confidential and that no personal information will be included in the study
report or other publication. ☐
4. I agree to take part in the above study ☐

Name of carer Date
Signature -----

Name of person taking consent Date
Signature -----

*When completed: 1 for patient, 1 for medical record (original), 1 for researcher site
file*

Appendix 13: HAPPI Statistical Analysis Plan

The Holistic Assessment and care Planning in Partnership Intervention Study (HAPPI)

A cluster randomised, controlled feasibility study of a nurse-led, holistic assessment and care planning intervention for older people living with frailty in primary care.

STATISTICAL ANALYSIS PLAN

Version 1.0 15/12/2019

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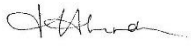


1. Study Summary

Study Title	<p>The Holistic Assessment and care Planning in Partnership Intervention Study [HAPPI]:</p> <p>A cluster randomised, controlled feasibility study of a nurse-led, holistic assessment and care planning intervention for older people living with frailty in primary care.</p>
Study Design	Feasibility, cluster randomised controlled trial with embedded qualitative study.
Study Participants	People aged 65 years and over who are moderately or severely frail.
Study Setting	General Practice populations in Cornwall, UK.
Intervention	<p>Delivery of the HAPPI intervention by trained community matrons in accordance with the conversation guide and assessment pack to ensure treatment fidelity. The intervention will be an individualised assessment and care planning process including development of person-centred goals supported by planning and relevant referrals. It will be carried out at the participant's home. Documentation of the intervention including assessment, individualised care and support plan and evidence of any referrals will be recorded using a standardised document/computerised template.</p>
Control	<p>Participants in the control group will receive usual care. This cannot be standardised as approaches to care of older people with frailty varies in general practice. This may include the management of various long-term conditions, referrals to other services, prescribing of medications and routine vaccinations. As part of the feasibility trial, components of usual care will be captured using a standardised proforma in order to describe this for the future definitive trial.</p>
Study duration	24 months
Nº of participants	60
Study Aims	<p>The primary aim of this cluster randomised, controlled feasibility study of a nurse-led Holistic Assessment and care Planning in Partnership Intervention (HAPPI) is to determine the feasibility of delivering the intervention in primary care to older people with frailty and to test potential trial methods to inform the design of a definitive randomised controlled trial (RCT).</p>

Inclusion criteria	<p>Potential participants will be eligible for the study provided they are:</p> <ul style="list-style-type: none"> k. Aged 65 years and over l. Moderately frail: Electronic Frailty Index (eFI) >0.24 to 0.36 or severely frail (eFI > 0.36) m. Frailty confirmed by PRISMA7 instrument n. Able to give informed consent o. Living in own home/supported living accommodation
Exclusion criteria	<p>Potential participants meeting any of the following criteria will be excluded from study participation:</p> <ul style="list-style-type: none"> f. Fit or mildly frail (eFI 0.13 – 0.24) g. Lives in a care home h. Patients in receipt of palliative care, on gold standards framework register or where clinician feels they have limited life expectancy i. Lacks mental capacity to give informed consent j. Patients already on the caseload of a Community Matron.
Key Milestones	<p>May 2018: Set up phase and recruit GP practices</p> <p>November 2018: Participant identification and eligibility check</p> <p>January 2019: Consent and baseline measures</p> <p>March 2019: Intervention</p> <p>June 2019: 3-month follow-up data collection</p> <p>November 2019: 6-month follow-up data collection</p>

2. Administrative Information

Title of Trial	The Holistic Assessment and care Planning in Partnership Intervention Study [HAPPI] A cluster randomised, controlled feasibility study of a nurse-led, holistic assessment and care planning intervention for older people living with frailty in primary care.
Trial registration number	ISRCTN 74345449
Protocol Version	2.1 18/03/2019
SAP Version	1.0
SAP Revisions	

	Name	Signature	Date
Statistical Analysis Plan Authored by:	Chief Investigator: Helen Lyndon		15/12/2019
	Statistician: Adam Streeter		09/01/2020
Approved by:	TSC Chair: Iain Lang		
	Independent Statistician: Chen Ji		02/01/2020

File Note: 28/01/2019

This final version of the SAP was discussed at the Trial Steering Committee (date 22/11/2019) and all comments were addressed. Due to unforeseen circumstances, the Chair is unable to sign off the SAP at finalisation.

3. Abbreviations

AE	Adverse Event
BGS	British Geriatrics Society
BI	Barthel Index
CGA	Comprehensive Geriatric Assessment
CRF	Case Report Form
EQ-5D-5L	European Quality of Life-5 Dimensions
fRCT	Feasibility Randomised Controlled Trial
HADS	Hospital Anxiety and Depression Scale
HAPPI	Holistic Assessment and care Planning in Partnership Intervention trial
LTC-6	Long Term Conditions 6-item Questionnaire
LUTS	Lower Urinary Tract Symptoms
MFRAT	Multifactorial Falls Risk Assessment Tool
PenCTU	Peninsula Clinical Trials Unit
PSP	Personalised Support Plan
RCT	Randomised Controlled Trial
SAE	Serious Adverse Events
SF-36	Medical Outcomes Study 36-Item Short Form Health Survey
TEP	Treatment Escalation Plan
TMG	Trial Management Group
TSC	Trial Steering Committee
UCLA-3	UCLA 3-item Loneliness Scale
VAS	Visual Analogue Scale

4. Introduction

4.1 Background and rationale for the trial

The full background and rationale for the trial can be found in the HAPPI study protocol V 2.1. The primary aim of this cluster randomised, controlled feasibility study of a nurse-led holistic assessment and care planning intervention is to determine the feasibility of delivering the intervention in primary care to older people with frailty and to test potential trial methods to inform the design of a definitive randomised controlled trial (RCT).

4.2 Purpose of statistical analysis plan

The trial protocol includes an outline of the statistical methods to be employed in the analysis of the trial data. The purpose of the Statistical Analysis Plan is to provide full details of the planned statistical methods to be used in the primary report of the trial results. HAPPI is a feasibility trial, therefore formal statistical analysis and hypothesis testing is not appropriate and thus will not be undertaken. This plan is based on “Guidance for the Content of Statistical Analysis Plans in Clinical Trials” (Gamble *et al.*, 2017).

5. Trial objectives and outcome measures

The objectives and outcome measures are taken from the study protocol version 2.1.

5.1 Objectives

- m. To assess compliance with the HAPPI intervention.
- n. To verify that proposed outcome measurement and follow-up schedules are feasible to collect.
- o. To determine achievable targets for recruitment and follow-up rates.
- p. To evaluate the method of recruitment using the electronic frailty index (eFI).
- q. To evaluate characteristics and feasibility of the proposed outcome measures and to determine suitable outcome measures for the definitive trial.
- r. To calculate estimates from the distribution of the measure identified as the primary outcome that may be used to inform the number of participants needed to be recruited to a definitive trial.
- s. To assess availability of clinical data and time needed to collect and analyse data required for numeric outcome measures.

- t. To explore factors that will enable future economic evaluation alongside the main trial. This will include an assessment of the feasibility of collecting EQ-5D-5L data which can be used to calculate quality-adjusted life years (QALYs).
- u. To determine acceptability of the intervention to participants, carers and clinicians in primary care.
- v. To assess barriers to delivery of the HAPPI intervention e.g. any operational difficulties within the community matron service.
- w. To evaluate clinicians' willingness to identify, recruit and randomise eligible patients, and willingness of patients to be recruited and randomised.
- x. To determine acceptability of trial processes and data collection to participants, sites and clinicians.

5.2 Outcome measures

The feasibility randomised controlled trial (fRCT) compares the delivery of the HAPPI intervention with usual primary care for frail older people. The outcomes relate to feasibility of the intervention, feasibility of conducting the trial and assessing potential primary and secondary outcomes for the future trial. These are summarised in Table 2:

Table 2: Summary of study objectives and outcome measures

Objective summary	Outcome measure (s)
Feasibility of the intervention	<ul style="list-style-type: none"> i. n/% of consented participants randomised to the intervention group who do not withdraw or die within the intervention period engaging with the minimum "dose" of the intervention ii. Number of staff moving between intervention and control GP practices
Feasibility of trial procedures including site feasibility, recruitment and retention	<ul style="list-style-type: none"> i. Number of GP practices expressing an interest in participating ii. Percentage of GP practices who were initially approached that participated iii. Number of GP practices screened for selection and reasons for non-selection iv. Number of GP practice withdrawing from the study, timing and reason for withdrawal v. Number of GP practices failing to progress through implementation milestones and reasons for failure vi. Number of GP practices withdrawing during the implementation and delivery phases vii. Numbers of participants identified using the electronic frailty index (eFI) as a denominator for number of those identified that are eligible

	<p>viii. Numbers of participants screened as eligible, recruited, consented and followed up</p> <p>ix. Number of and timing of participant withdrawals from follow-up data collection, reasons for withdrawal, number of and timing of losses to follow-up</p>
Assessing different potential primary and secondary outcomes of the future trial	<p>i. Numbers of potential primary and secondary outcome measures completed at baseline and follow-up intervals</p> <p>ii. Numbers of missing items for each potential primary and secondary outcome at each time-point</p> <p>iii. Assessment of the feasibility of collecting data to estimate cost-effectiveness using the EQ-5D-5L</p> <p>iv. Assessment of the suitability/feasibility of delivering the following outcome measure instruments:</p> <ul style="list-style-type: none"> • Levels of loneliness and isolation measured by UCLA 3-Item Loneliness Scale • Physical health and mobility, level of pain, mood and emotional health and health-related quality of life measured by the Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36) • Confidence in own ability to manage health, as participants in care measured by the Health Foundation LTC6 questionnaire • Mortality; date and cause of death obtained from the clinical record • Number of hospital admissions, readmissions and total number of days spent in hospital obtained from the clinical record <p>v. Polypharmacy – number of medications prescribed in total at study time points</p>

All clinical outcome measures will be conducted at baseline (T1), three months (T2) and six months (T3).

6. Study Methods

6.1 Trial design

A feasibility, cluster randomised controlled trial with embedded qualitative study for older people who live with moderate or severe frailty in a primary health care setting. The study aimed to recruit 60 participants from 6 general practices in Cornwall using

the electronic frailty index (eFI) as the initial identification method and random sampling. Randomisation occurred at general practice level with participants from three practices allocated to the control group and participants from three general practices allocated to intervention. Control participants receive care as usual, intervention participants receive the HAPPI intervention.

6.2 Eligibility Criteria

The trial population will be people who are:

- i. Aged 65 years and over
- ii. Moderately frail: Electronic Frailty Index (eFI) >0.24 to 0.36 or severely frail (eFI > 0.36)
- iii. Frailty confirmed by PRISMA7 instrument
- iv. Able to give informed consent
- v. Living in own home/supported living accommodation

People meeting any of the following criteria are excluded from participating in the trial:

- i. Fit or mildly frail (eFI 0.13 – 0.24)
- ii. Lives in a care home
- iii. Patients in receipt of palliative care, on gold standards framework register or where clinician feels they have limited life expectancy
- iv. Lacks mental capacity to give informed consent
- v. Patients already on the caseload of a Community Matron.

6.3 Randomisation and Allocation Concealment

In order to avoid contamination of the control group, this study was designed as a feasibility pragmatic cluster RCT with randomisation at general practice level.

Randomisation took place following recruitment of all six sites and prior to consent and baseline outcome measures assessment. Sites were randomised into allocated groups of equal size, so that the control and intervention groups each comprised three randomly allocated. This was performed by an independent statistician, external to the trial, to maintain blinding of the trial statistician. Allocation was revealed to sites once potential participants had been identified and screened for

eligibility. The full randomisation specification and the programming code used is included as Appendix 1.

6.4 Blinding

Due to the nature of the intervention, it was not possible to blind the trial participants or community matrons delivering the intervention. It is also not possible for the Chief Investigator to remain blinded as she was responsible for training the community matrons to deliver the intervention. However, assessors were blinded, and participants asked not to reveal their treatment allocation during assessments.

6.5 Sample size

It is not appropriate in a feasibility study to calculate sample size based on considerations of power (Thabane *et al.*, 2010). This study is not powered to detect clinically meaningful between-group differences in a primary outcome. There is no consensus in the literature on the recommended number of participants required for a feasibility study, with suggested numbers ranging from 20 to 70 or more participants when the planned primary outcome is of a continuous nature (Whitehead *et al.*, 2016).

This feasibility study aimed to recruit 60 participants in total. Ten participants at each site were identified as a reasonable compromise between collecting information about the viability of conducting a larger trial and available resources for implementing this feasibility study. Participants were recruited from six general practices, with a total practice population of 491,000. Recruitment took place over a six month period and it was anticipated that following initial screening using the electronic frailty index (eFI), approximately 9000 (1500 per practice) potential participants would be identified and from these 540 (90 per practice) sampled for second screening for eligibility according to the PRISMA7 instrument (Appendix 11). A maximum recruitment rate was set at 10 participants per month across all sites. Numbers of participants screened and randomised by site will be reported as in Table 3. The follow-up rate is estimated to be 70%, which would provide full outcome data on a minimum of 42 participants across both allocated groups.

6.6 Sampling Methods

The total number of patients within each eFI stratum was determined at each site. Each site, therefore, provided two lists (one for each stratum) with the date of their generation. Each patient was uniquely identified by a number ranging from one to the number of patients in each stratum at each site. The statistician generating the sampling sequence provided each practice with a list of random numbers based on the total number of patients in each stratum in the order they were to be approached for eligibility. If an insufficient number of patients consented to participate from any strata, then the sampling process was repeated (without replacement) for that stratum, from the remaining list of unsampled patients either until five patients were recruited for each stratum or until no further patients were available. The full sampling specification is included as Appendix 2.

6.7 Timing of final analysis

Statistical analysis will be undertaken once final data collection has occurred and the database is locked.

7. Statistical Methods.

7.1 Statistical significance Levels

As a feasibility trial, there will be no hypothesis testing undertaken.

7.2 Adherence and protocol deviations

Non-compliance with the trial protocol may occur in two ways. Firstly participants may not complete the minimum dose of the intervention according to the protocol. This may occur due to illness, admission to hospital, increasing frailty or if the participant makes the decision not to continue with the intervention. The number and proportions of participants categorised as non-compliant will be summarised as will all observed outcomes by allocated group. Secondly sites may not comply with protocol procedures relating to screening and recruitment. This is be recorded using the trial non-compliance form and numbers and types of instances of non-compliance will be summarised by site (Table 4).

7.3 Analysis populations

Primary analysis (in the form of summary statistics, not formal analysis) will be undertaken based on intention to treat (ITT) descriptive analysis. There will be comparison of a per-protocol subset of intervention participants versus the ITT intervention group versus the control group. As a feasibility study the differences will not be tested for statistical significance i.e.: p-values will not be calculated and statistical inference will not be made from confidence intervals.

If there are any cases of missing follow-up outcome data, the associated participant(s) will be removed from the analysis. This will enable exploration of what happens if varying number of questions are not answered or missing, and help to set a cut-off value.

7.4 Data Sources and Data Quality

The data from this trial will come from information entered onto Case Report Forms (CRFs) completed by community matrons delivering the intervention, blinded assessors at baseline and general practice staff from the clinical record. In addition outcome measure questionnaires are completed at baseline, three months and six months.

7.5 Trial population

Data from the screening process through to the completion of the trial will be recorded and presented following The Consolidated Standards of Reporting Trials (CONSORT) guidelines for pilot and feasibility trials (Eldridge *et al.*, 2016) (Figure 1).

7.6 Participants who discontinue, withdraw or are lost to follow-up

It is possible that participants will withdraw consent partway through the trial, or their treatment may be discontinued due to medical reasons. Reasons for withdrawal or loss to follow up will be summarised, when reported, in the CONSORT diagram (Figure 1) and by site in Table 4.

Participants who withdraw from the trial will not be replaced although their available data will be used unless they have specifically requested for it to be removed from

the database. The extent of discontinuation, withdrawal and loss to follow up will be used to inform the design of the fully powered subsequent trial to ensure a sufficiently powered trial after drop-out.

8. Statistical Analysis

8.1 Statistical software

The statistical analyses will be undertaken using Statistical Package for the Social Sciences (SPSS) version 24(IBM Corporation, Released 2016).

8.2 Assessment of baseline variables

The following baseline variables will be summarised by allocated group:

- i. Demographics (age, gender, relationship status, living arrangements).
- ii. Frailty severity

For full details of included variables see Table 5.

8.2 Assessment of recruitment, retention and adherence

Numbers of participants screened, eligible, randomised, consented and withdrawn from the study will be reported by trial site and in total. Numbers will be reported for the intervention group and control group. The information will be summarised as a CONSORT flow diagram (Figure 1). Reasons for exclusion and for withdrawal will be summarised, where reported.

Baseline demographic and clinical data will be summarised for the ITT population, for each of the two treatment groups and overall.

Continuous variables will be summarised as mean (standard deviation) and median (interquartile range) whilst categorical variables will be summarised by the frequency of each level and their percentage of each group. There will be no statistical testing for any of the summary measures whilst comparing the variables between the treatment groups. Where appropriate, uncertainty around estimates of candidate primary outcomes may be expressed with 95% confidence intervals.

8.3 Feasibility parameters

Feasibility parameters will be reported that relate to the feasibility of trial procedures including site processes, recruitment, retention and ability to collect outcome measures data (Table 3, Table 4, Table 10). Other feasibility indicators relate to testing the intervention and include retention and adherence to the intervention (Table 4).

8.4 Intervention delivery/refinement

Treatment fidelity will be measured by the percentage of participants who receive the minimum “dose” of the intervention which is defined as one assessment visit and at least two care planning visits (Table 4). The content of the intervention will be refined for the definitive trial by evaluating the number of each type of assessment from the intervention pack that are completed (Table 7) and the number of referrals to other services made (Table 8). In addition, number of referrals per participant and average number of referrals will be calculated.

8.5 Assessment of outcome measures

The feasibility of the proposed outcome measures will be evaluated by the number of outcome measures completed at T1, T2 and T3. This criterion will help inform the choice of primary outcome measure or, potentially, multiple outcomes requiring multivariate analysis within a definitive trial. The feasibility trial gives the opportunity to ascertain, which outcome measures are acceptable to the participants; which can be administered in primary care; and which are sensitive to change at the different time points. Outcome measure data will be reported by group as in Table 10.

Physical health and mobility, level of pain, mood and emotional health and health-related quality of life measured by the Medical Outcomes Study 36-Item Short Form Survey Instrument Version 1 (SF-36) (Ware & Sherbourne, 1992).

There is evidence for reliability, validity and responsiveness of this measure and it is particularly recommended where a detailed and broad ranging assessment of health is required, particularly in community dwelling older people (Haywood, Garratt & Fitzpatrick, 2005). The SF-36 examines eight health concepts and each concept has an individual range of values as follows:

1. Physical functioning: 10 items, range = 0 -1000.
2. Role limitations due to physical health problems: 4 items, range = 0-400
3. Bodily pain: 2 items, range = 0-200
4. General health perceptions: 5 items, range = 0-1400
5. Vitality: 4 items, range = 0-400
6. Social functioning: 2 items, range = 0-200
7. Role limitations due to emotional health problems: 3 items, range = 0-300
8. Mental health: 5 items, range = 0-500

Plus a single item on reported health transition: 1 item, range = (0-100).

A global measure of health-related quality of life cannot be generated from the questionnaire (Lins & Carvalho, 2016). The lower the score on each concept, the higher the level of disability.

Confidence in own ability to manage health and in role as participants in care measured by the Health Foundation LTC6 questionnaire. This measure asks patients with a long term condition about their experience and understanding of their healthcare over the last 12 months. It includes questions about involvement in decision- making and support for self-management (Health Foundation 2013). Range of values 0-18 with a higher score indicating higher levels of confidence.

Levels of loneliness and isolation measured by UCLA 3-Item Loneliness Scale. This scale measures the impact of loneliness in later life (Gale, Westbury & Cooper, 2018). It has been found to be a reliable and valid measure of loneliness by comparing the results against a self-identifying statement and validated for self-completion and by completion by interview (Hughes *et al.*, 2004). Range of values 3-9, scores 2-5 indicate “not lonely”, 6-9 indicate “lonely”.

Function measured by the Barthel Index (BI) (Mahoney & Barthel, 1965) The BI rates a person’s degree of independence performing functional self-care (feeding, grooming, bathing etc.) and mobility activities (transferring in/out of bed/chair, walking etc.). Range of values 0 – 20 with lower scores indicating increased disability.

Feasibility of collecting data for future economic evaluation measured by the EQ-VAS (5L version) (Janssen *et al.*, 2013). This visual analogue scale can also be used to measure quality of life, however, in this trial it is used only to test feasibility of obtaining data. For a future RCT this can then be used in the calculation of quality-adjusted life years within an overall economic evaluation. In addition to the VAS there is a 25- item descriptive system comprised of the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. Ticking a box results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the respondent's health state. It should be noted that the numerals 1-5 have no arithmetic properties and, therefore, a summary index number is not recommended:

Level 1: indicating no problem

Level 2: indicating slight problems

Level 3: indicating moderate problems

Level 4: indicating severe problems

Level 5: indicating extreme problems

Data from the descriptive system will be presented as percentage of intervention and control participants reporting levels 1 to 5.

EQ VAS values will be presented by intervention and control groups; mean + standard deviation and median + interquartile range. In addition, numbers and proportions of participants reporting levels within the EQ-5D-5L dimensions will be reported by intervention and control (Table 11).

8.6 Identification of the primary outcome

Conditional on the completeness of the candidate outcomes at baseline and the follow-up visits, an initial indication of possible efficacy in a future definitive trial and the power to detect such an outcome will be in part determined by consideration of the possible detectable effect size in a future definitive trial. Detection of an effect depends on the size of the standard deviation (SD) relative to the difference between allocated groups in the change in the outcome since baseline.

Differences in each outcome between baseline and three months, and baseline and six months shall be calculated. The difference (Δ) between each arm in the mean change in the outcome divided by the pooled standard deviation from each arm yields the estimated effect size:

$$Effect\ size = \frac{Mean\ change\ in\ intervention\ group - mean\ change\ in\ control\ group}{Standard\ deviation_{pooled}}$$

The number needed for a future definitive trial testing the intervention with 5% significance and 90% power can be calculated from the formula:

$$n \geq \frac{2(z_{\alpha} + z_{1-\beta})^2}{effect\ size}$$

Assuming an intra-cluster correlation coefficient (ICC) of 0.05 and cluster size of 10 in a future trial (as in this trial), this yields an design effect of $1 + 0.05*(10-1)=1.45$.

The numbers required to detect a given effect size are, therefore, derived as:

Effect size	Minimum n	Sample size inflated for cluster sizes of 10 patients per practice
0.1	857	1243
0.2	215	312
0.3	96	140
0.4	54	79
0.5	35	51

Given it would not be unfeasible for a future trial to recruit 312 participants in this population, a modest effect size of 0.2 could be detected at 5% significance with 90% power from centres with an ICC of 0.05. On the scale of change since baseline in any one of the potential primary outcomes, the common standard deviation, SD , would therefore have to be no more than five times the difference, Δ , between the allocated groups (i.e. $SD < 5\Delta$ since $\Delta/SD \geq 0.2$).

However, the population standard deviation (δ) is necessarily estimated with error by the sample SD. For a unit SD (i.e. SD=1), the limits for the 95% confidence intervals associated with sample size, n, can be seen to stabilise after a sample size of 30 (Figure 4).

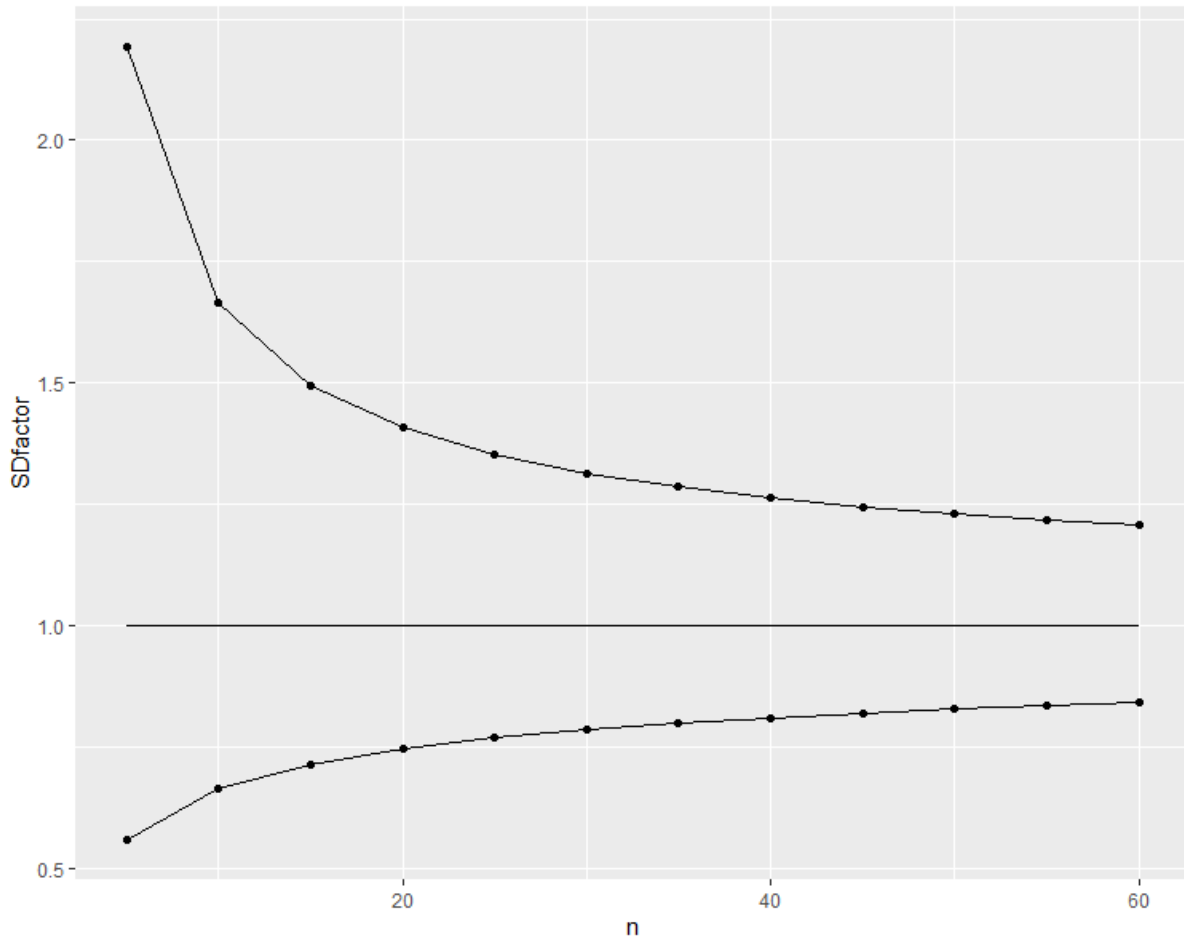


Figure 4: Plot of 95% confidence intervals for the sample standard deviation expressed as a factor (SDfactor) of SD=1 against sample size, n.

From an initial target of 60 participants to be recruited, over half could be reasonably expected to provide data on the outcomes of interest. Furthermore, since the upper confidence limit (CL) would be critical in determining the sample size, then a one-sided CL is estimated at the 5% significance level. Therefore, from a sample size of

$n = 30$, the upper 95% CI level is $SD_{Lower95\%CI} = \sqrt{\frac{(n-1)s^2}{\chi_{0.95}^2(df=n-1)}} = \sqrt{\frac{29}{17.7}} s \approx 1.3s$

Therefore adjusting the size of the standard deviation relative to the difference between groups, the sample standard deviation needs to be less than 4 times (5/1.3 \approx 4) the difference between allocated groups, i.e. $SD < 4\Delta$.

8.7 Missing data

Completeness of the data is an important feasibility parameter for all outcome measures. The proportion of participants missing each outcome will be summarised for each allocated group and at each time point, with reasons for missing outcomes documented wherever possible (Table 12). Data could be missing for a number of reasons:

1. Participant opts out of trial before follow-up data collection
2. Participant refuses to participate in collection of measures
3. Participant is uncontactable
4. Participant moves out of the trial geographical area before follow-up data collection
5. Participant is medically unwell or receiving end of life care
6. Participant dies and is withdrawn from the trial.

Missing outcome data will be noted and used to inform the likely pattern of missing data in a full-scale trial. If a considerable amount of outcome data is missing, this may suggest a need to reconsider the choice of outcome measures. This may also provide an insight into how missing data can be avoided in the subsequent full-scale trial.

8.8 Safety

Safety of the intervention will be measured by the number of adverse events and serious adverse events relating to the intervention that occur during the intervention period. Community matrons will be responsible for reporting any AEs that are related to the intervention or SAEs. Safety during data collection will be assessed by the number of adverse events or serious adverse events that occurred during the follow-up period. The blinded assessors are responsible for recording any adverse events that occurred during data collection.

The adverse event (AE) risks of taking part in this trial have been assessed to be low. This is an assessment and care planning intervention which is unlikely to cause any harm to participants. In this patient population of moderately and severely frail patients, acute illness resulting in hospitalisation, new medical problems and deterioration of existing medical problems are expected. For participants in this study who are moderately or severely frail, this will include SAEs relating to frailty syndromes such as admission to hospital for abrupt onset of falls, immobility, delirium caused by infection/sepsis, incontinence and iatrogenic side effects of medication. Therefore, only AEs which relate to the intervention will be recorded and assessed for severity and causality.

Serious adverse events are classified as:

- results in death
- is life threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- consists of a congenital anomaly or birth defect
- or is considered by the investigator to be an important medical event

All adverse and serious adverse events will be reported for the intervention group only and assessed for clinical relevance to inform the design and conduct of a full trial (Tables 13 and 14).

8.9 Criteria for progression to full trial

Progression to a full trial will be considered viable if the pre-specified criteria are met or if clear strategies are identified that could support the delivery of the definitive trial in tandem with successfully identifying a suitable primary outcome. The success criteria are listed in Table 2 and denoted against a traffic light criteria (Battle *et al.*, 2019):

- Green indicates the target was achieved

- Amber indicates the target was not achieved but progression to full trial would be possible with minor protocol amendments
- Red indicates the target was not achieved and progression to full trial is unlikely to be supported

Table 2: Criteria for progression to full trial

Feasibility success criteria	Green	Amber	Red
% of general practice sites that were initially approached and progressed to participating in the study	≥ 50%	41-49%	≤ 40%
% of recruitment target achieved (60 participants) in the timescale of 43 weeks (01/11/2018-31/08/2019)	≥50%	41-49%	≤40%
% of participants completing 3 month follow up	≥80%	51-79%	≤50%
% of participants completing 6 month follow up	≥70%	51-69%	≤50%
% of consented participants randomised to the intervention group who do not withdraw or die within the intervention period engaging with the minimum “dose” of the intervention which is defined as one assessment visit and at least two care planning visits	≥75%	51-74%	≤50%

9. Qualitative Analysis

This component of the trial explores the experiences of the study participants, their carers and the experiences of the clinicians who have delivered the intervention and GP practice staff who facilitated recruitment and eligibility screening. The aim is to generate recommendations and address unknowns including experiences of recruitment, retention, practical implementation and further refinement of the intervention and outcome measures for the design of the future RCT. Qualitative study results will be reported using the COREQ checklist for interviews and focus groups (Tong, Sainsbury & Craig, 2007). Thematic analysis will be used to analyse the data. This method includes a strategy for identifying themes and subthemes

(Braun & Clarke, 2006). The transcripts of the interviews will be uploaded to the qualitative analysis program NVivo.

The first analysis step will involve familiarisation of the narratives and two researchers will independently read the transcripts. In the next step, two researchers will independently code the text by allocating the text fragments to codes. The codes will be formulated from the text fragments and will possibly be revised during the process of reading the transcripts. The two researchers will then discuss the results of the individual codes and try to reach consensus. After this, the codes will be reviewed and themes will be formulated.

9.1 Qualitative data presentation

Demographic data items will be presented using descriptive statistics. Meaningful text fragments will be determined, as will codes (sub-themes) and themes related to the trial objectives. Data extracts will be accompanied by narrative to elaborate why the extract is analytically interesting. All participants will be anonymised and pseudonyms used to demonstrate different participants' experiences. If any information is disclosed during the trial that could pose a risk of harm to the participant or others, the CI where appropriate, will report and act accordingly.

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11. Appendices

Appendix 1: Randomisation Specification

CHIEF INVESTIGATOR	TRIAL STATISTICIAN	STATISTICIAN GENERATING ALLOCATION SEQUENCE
<p>Helen Lyndon Room S09, School of Nursing and Midwifery, Faculty of Health and Human Sciences, University of Plymouth, Knowledge Spa, Royal Cornwall Hospital, Treliske, Truro, Cornwall, TR1 3HD Helen.lyndon@plymouth.ac.uk Telephone: 07919891065</p>	<p>Adam Streeter N15, Medical Statistics, ITTC1 Plymouth Science Park, Plymouth, PL6 8BX adam.streeter@plymouth.ac.uk Telephone: 01752 764203</p>	<p>Joanne Hosking N15, Medical Statistics, ITTC1 Plymouth Science Park, Plymouth, PL6 8BX joanne.hosking@plymouth.ac.uk Telephone: 01752 764203</p>

PROTOCOL VERSION:	V 2.0
SETTING:	General Practice populations in Cornwall, UK
PERSONNEL:	CTU staff
RECRUITMENT TARGET:	6 General Practices
ALLOCATION RATIO:	1:1
TREATMENT GROUPS:	HAPPI, Control
BLINDING STATUS:	Research nurses / Trial assessors
START DATE / END DATE:	January 2019 / April 2020
IMPLEMENTATION:	Notification by data managers at CTU
RANDOMISATION METHOD:	Simple
STRATIFICATION VARIABLES:	N/A
METHOD DETAILS:	Static randomisation
SEQUENCE GENERATION:	<p>R version 3.5.1 (2018-07-02)</p> <pre>gplist <- c("The Clays Practice, Roche", "St Austell Health Group", "The Roseland Practice, Portscatho", "The Alverton Practice, Penzance", "Carn to Coast Health Centres, Redruth, Pool and Illogan", "Three Spires Medical Centre, Truro")</pre>

	<pre>gp1 <- as.data.frame(gplist) N <- nrow(gp1) set.seed() gp1\$randnum <- runif(N) gp1 <- gp1[order(gp1\$randnum),] gp1\$allocation <- c('I', 'I', 'I', 'C', 'C', 'C')</pre>
--	---

FURTHER DETAILS:

I = HAPPI intervention

C = control

Finalised specification agreed and approved by:

Trial statistician

Name: Signature: Date:

CTU lead developer

Name: Signature: Date:

Independent statistician

Name: Signature: Date:

For CTU office use only

CONFIRMATION OF ALLOCATION SEQUENCE RECEIPT <enter N/A if not applicable>

The following items have been received by the PenCTU lead developer and stored securely in a password-protected location:

File of code used to generate the sequence (with version number and date)

Allocation sequence generation seed number

Allocation sequence output (with version number and date)

Tick to confirm

NB: THE ABOVE ITEMS MUST NOT BE SHARED WITH THE TRIAL STATISTICIAN

Confirmation:

Name:

Signature:

Appendix 2: Sampling Specification

HAPPI STUDY SAMPLING SPECIFICATION FORM

CHIEF INVESTIGATOR	TRIAL STATISTICIAN	STATISTICIAN GENERATING SAMPLING SEQUENCE
Helen Lyndon Room S09, School of Nursing and Midwifery, Faculty of Health and Human Sciences, University of Plymouth, Knowledge Spa, Royal Cornwall Hospital, Treliske, Truro, Cornwall, TR1 3HD Helen.lyndon@plymouth.ac.uk Telephone: 07919891065	Adam Streeter N15, Medical Statistics, ITTC1 Plymouth Science Park, Plymouth, PL6 8BX adam.streeter@plymouth.ac.uk Telephone: 01752 764203	Joanne Hosking N15, Medical Statistics, ITTC1 Plymouth Science Park, Plymouth, PL6 8BX joanne.hosking@plymouth.ac.uk Telephone: 01752 764203

PROTOCOL VERSION:	V 1.0
SETTING:	General Practice populations in Cornwall, UK
PERSONNEL:	CTU staff
RECRUITMENT TARGET:	6 General Practices
ALLOCATION RATIO:	1:1
TREATMENT GROUPS:	HAPPI, Control
BLINDING STATUS:	Research nurses / Trial assessors
START DATE / END DATE:	January 2019 / April 2020
IMPLEMENTATION:	Notification by data managers at CTU
STRATIFICATION VARIABLES:	Electronic frailty index: 1. Moderately frail (0.24, 0.36] 2. Severely frail (0.36, 1.00]
METHOD DETAILS:	Static randomisation

Sampling procedure

The number of patients within each eFI stratum shall be determined at each site. Once the total number of patients with an eFI available has been determined, each site shall save 2 lists

(one for each stratum) with the date of their generation. Each patient shall be uniquely identified by a number ranging from one to the number of patients in each stratum. , The statistician generating the sampling sequence shall send each practice a list of random numbers based on the total number of patients in each stratum in the order they are to be approached for eligibility. Therefore the steps shall be:

1. Each General Practice (GP) collates two lists of patients, for whom eFIs are available, and whose eFIs are greater than 0.24, but not more than 0.36 (moderately frail), or greater than 0.36 (severely frail).
2. For the purpose of sampling, the patients will be identified by the number pertaining to the order they appear in the list. This number should be retained until the sampling procedure has been completed.
3. The CI shall communicate to the statistician generating the sampling sequence (SGSS):
 - a. the number of patients in each stratum at each GP
 - b. the stratum label (moderate or severe)
 - c. the GP site.
4. The SGSS shall then draw a random sample (without replacement) of 45 patients from each stratum of each GP, based on a uniform distribution with a maximum pertaining to the number of available patients in each eFI stratum of each GP. Where this number is less than 45, then no random sampling list is required and all available patients within the stratum will be considered for the next stage of having their eligibility checked against the selection criteria.
5. Once a randomised list for GP is passed back to the CI, the patients should be assessed for eligibility in the order stipulated on the randomised sample list.

If an insufficient number of patients consent to participate from any strata, then the sampling process shall be repeated (without replacement) for that stratum, from the remaining list of unsampled patients until either five patients are recruited or no further patients are available.

Finalised specification agreed and approved by:

Trial statistician

Name:

Signature:

Date:

Chief Investigator

Name:

Signature:

Date:

Appendix 3: Figures and Tables

Figure 1: CONSORT Flow Diagram of participants in HAPPI Trial

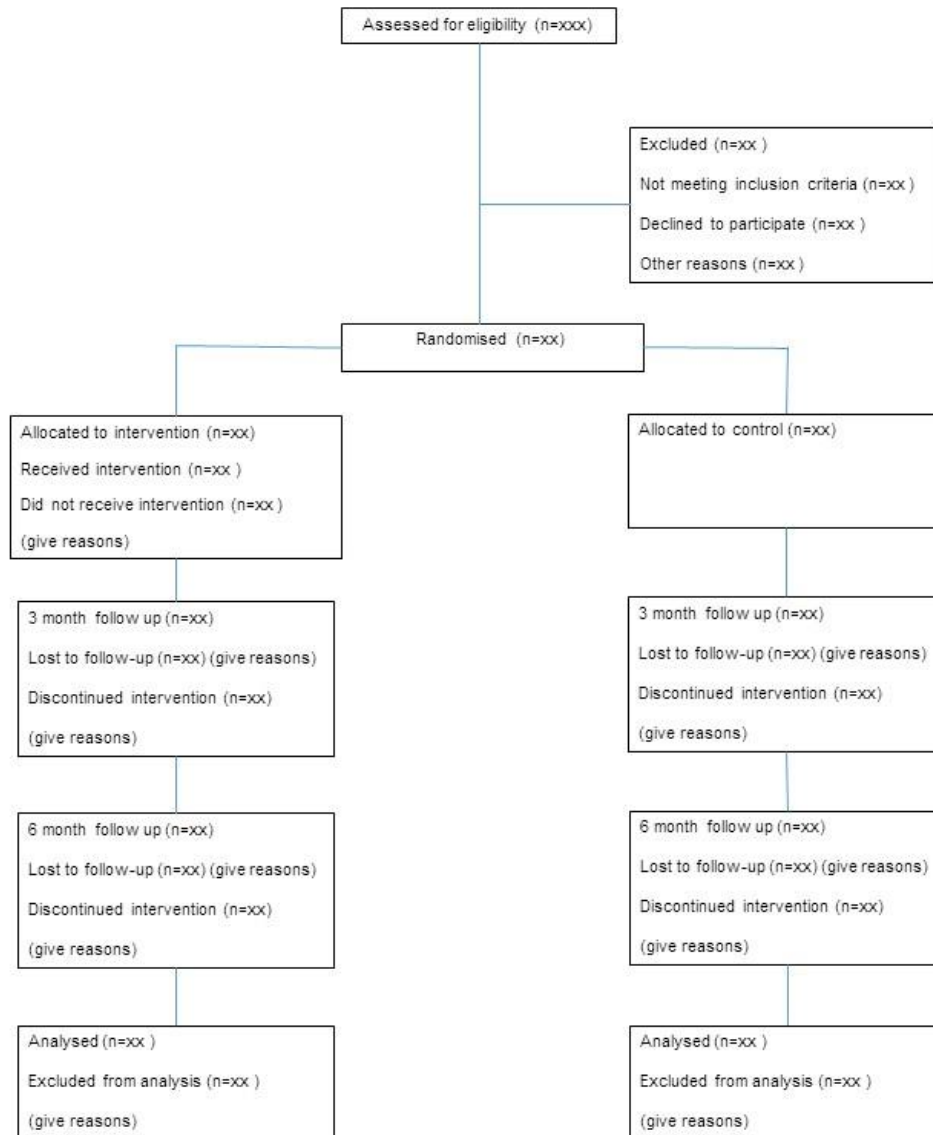


Table 3: Number of participants screened and randomised by site

	Intervention sites			Control sites		
Variable	Site 01	Site 02	Site 05	Site 03	Site 04	Site 06
Numbers n (%) screened						
Total	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Reasons for non-participation (n)						
Did not meet inclusion criteria	xx	xx	xx	xx	xx	xx
Declined to participate or did not respond to invitation	xx	xx	xx	xx	xx	xx
Other reasons	xx	xx	xx	xx	xx	xx
Number n (%) randomised						
Total	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number n (%) discontinuation/withdrawal						
Total	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number n (%) of participants data analysed						
Total	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

Table 4: Retention of participants

	Intervention sites			Control sites		
Variable	Site 01	Site 02	Site 05	Site 03	Site 04	Site 06
Number (%) (ratio) of randomised participants who completed three month follow up	nn/xx	nn/xx	n/xx	n/xx	nn/xx	nn/xx
Total	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number (%) (ratio) of randomised participants who completed six month follow up	nn/xx	nn/xx	n/xx	n/xx	nn/xx	nn/xx
Total	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of randomised participants with no protocol deviations – adherence to intervention dose	nn/xx	nn/xx	n/xx	N/A	N/A	N/A
Number of operational protocol deviations	xx	xx	xx	xx	xx	xx

Number of patient related protocol deviations	xx	xx	xx	xx	xx	xx
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Table 5: Baseline variables by group

Variable		Intervention (n=xx)	Control (n=xx)
Age (years)	Mean (SD) [range]	xx (xx.x)[x-x]	xx (xx.x)[x-x]
	Median (IQR)	xx(xx)	xx(xx)
Gender n (%)	Male	xx (xx.x)	xx (xx.x)
	Female	xx (xx.x)	xx (xx.x)
Relationship Status n (%)	Single	xx (xx.x)	xx (xx.x)
	Married/civil partnership	xx (xx.x)	xx (xx.x)
	Divorced/civil partnership dissolved	xx (xx.x)	xx (xx.x)
	Widowed/surviving civil partner	xx (xx.x)	xx (xx.x)
Living arrangements n (%)	Alone	xx (xx.x)	xx (xx.x)
	Spouse/Partner	xx (xx.x)	xx (xx.x)
	Parent/s	xx (xx.x)	xx (xx.x)
	Children under 18	xx (xx.x)	xx (xx.x)
	Children over 18	xx (xx.x)	xx (xx.x)
	Other family	xx (xx.x)	xx (xx.x)
	Non-family	xx (xx.x)	xx (xx.x)
Frailty Severity n (%)	Moderately frail	xx (xx.x)	xx (xx.x)
	Severely frail	xx (xx.x)	xx (xx.x)

Table 6: Site feasibility

Variable	
Number (%) of general practice sites who were initially approached progressed to participating in the study	xx(xx.x)
Number (%) (ratio) of practices approached who met initial eligibility criteria	
Number (%) of general practice sites who withdrew from the study prior to completion	xx(xx.x)
Number (%) of sites completing screening/eligibility processes as per study protocol	xx(xx.x)
Number (%) of sites completing screening/eligibility processes within prescribed timescale (6 months from site initiation)	xx(xx.x)

Table 7: Frequency of intervention assessment documents used at specific intervention time points

Number (n) of assessment documents used at each visit	Visit 1 (n)	Visit 2 (n)	Visit 3 (n)	Visit 4 (n)	Visit 5 (n)	Visit 6 (n)	Total (n)
Conversation Guide	xx	xx	xx	xx	xx	xx	xx
Gait Speed Test	xx	xx	xx	xx	xx	xx	xx
Clinical Frailty Scale	xx	xx	xx	xx	xx	xx	xx
MFRAT	xx	xx	xx	xx	xx	xx	xx
FRAX tool	xx	xx	xx	xx	xx	xx	xx
Numeric pain scale	xx	xx	xx	xx	xx	xx	xx
Pain assessment record	xx	xx	xx	xx	xx	xx	xx
Abbey Pain Scale	xx	xx	xx	xx	xx	xx	xx
Medication review	xx	xx	xx	xx	xx	xx	xx
STOPP-START	xx	xx	xx	xx	xx	xx	xx
MUST 5 Step Guidance	xx	xx	xx	xx	xx	xx	xx
MUST Flowchart	xx	xx	xx	xx	xx	xx	xx
MUST Screening Tool	xx	xx	xx	xx	xx	xx	xx

RCP Bedside Vision	xx	xx	xx	xx	xx	xx	xx
Whispered Voice Test	xx	xx	xx	xx	xx	xx	xx
Clinical Checklist LUTS	xx	xx	xx	xx	xx	xx	xx
ICIQ Bladder Diary	xx	xx	xx	xx	xx	xx	xx
Self-assessment LUTS	xx	xx	xx	xx	xx	xx	xx
Bowel Assessment Form	xx	xx	xx	xx	xx	xx	xx
Checklist Faecal Incontinence	xx	xx	xx	xx	xx	xx	xx
BGS CGA and Problem List	xx	xx	xx	xx	xx	xx	xx
CFT TEP	xx	xx	xx	xx	xx	xx	xx
Barthel Index	xx	xx	xx	xx	xx	xx	xx
UCLA 3-Item Loneliness Scale	xx	xx	xx	xx	xx	xx	xx
Caregiver Strain Index	xx	xx	xx	xx	xx	xx	xx
CFT Capacity Assessment	xx	xx	xx	xx	xx	xx	xx
CAM Delirium Screening Tool	xx	xx	xx	xx	xx	xx	xx
GPCog	xx	xx	xx	xx	xx	xx	xx
Geriatric Depression Score	xx	xx	xx	xx	xx	xx	xx
HADS	xx	xx	xx	xx	xx	xx	xx
CFT PSP: Part 1	xx	xx	xx	xx	xx	xx	xx
CFT PSP:	xx	xx	xx	xx	xx	xx	xx

Table 8: Frequency of type of referrals made at intervention time points

Number (n) of referrals made at each visit	Visit 1 (n)	Visit 2 (n)	Visit 3 (n)	Visit 4 (n)	Visit 5 (n)	Visit 6 (n)	Total (n)
General Practitioner	xx	xx	xx	xx	xx	xx	xx
Geriatrician	xx	xx	xx	xx	xx	xx	xx
Physiotherapy	xx	xx	xx	xx	xx	xx	xx
Occupational Therapy	xx	xx	xx	xx	xx	xx	xx
Speech Therapy	xx	xx	xx	xx	xx	xx	xx
Dietician	xx	xx	xx	xx	xx	xx	xx
Intermediate Care	xx	xx	xx	xx	xx	xx	xx
Adult Social Care	xx	xx	xx	xx	xx	xx	xx
Continuing Care	xx	xx	xx	xx	xx	xx	xx
District Nurses	xx	xx	xx	xx	xx	xx	xx
Falls Clinic	xx	xx	xx	xx	xx	xx	xx
Dementia Services	xx	xx	xx	xx	xx	xx	xx
Voluntary Sector	xx	xx	xx	xx	xx	xx	xx
Other	xx	xx	xx	xx	xx	xx	xx

Table 9: Number of referrals per participant at intervention time points

Number (n) of referrals	Visit 1 (n)	Visit 2 (n)	Visit 3 (n)	Visit 4 (n)	Visit 5 (n)	Visit 6 (n)	Overall (n) Median (IQR)
Participant number	xx	xx	xx	xx	xx	xx	xx (xx.x)

Table 10: Participant Outcome Data

Variable		Intervention Group			Control Group		
Timepoint		T1	T2	T3	T1	T2	T3
SF-36							
<i>Physical functioning: Items 3a, 3b, 3c, 3d,3e,3f,3g,3h,3i,3j</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
<i>Role-physical: Items 4a,4b,4c,4d</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
<i>Bodily pain: Items 7,8</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
<i>General Health: Items 1,11a,11b,11c,11d</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
<i>Vitality: Items 9a,9e,9g,9i</i>	Mean (SD) [range]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]

	Median (IQR)						
<i>Social functioning: Items 6,10</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
<i>Role-emotional: Items 5a,5b,5c</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
<i>Mental health: Items 9b,9c,9d,9f,9h</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
<i>Reported health transition: Item 2</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
LTC-6	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
UCLA-3	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Barthel Index	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
EQ-5D-5L							
Mobility (levels1-5)	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Self-care (levels1-5)	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Usual activities (levels1-5)	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]

<i>Pain/discomfort (levels 1-5)</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
<i>Anxiety/depression (levels 1-5)</i>	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
EQ-5D-5L VAS	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Number of deaths	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Cause of death	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Number of hospital admissions	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Number of hospital readmissions	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Total number of days spent in hospital	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]
Number of prescribed medications	Mean (SD) [range] Median (IQR)	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]	xx.x(xx.x)[x-x]

Table 11: Numbers and proportions reporting levels within EQ-5D-5L dimensions by intervention and control

	Mobility		Self-care		Usual activities		Pain		Anxiety/depression.	
Level n (%)	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
01 No problems	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
02 Slight problems	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
03 Moderate problems	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
04 Severe problems	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
05 Extreme problems	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number reporting some problems (02-05)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Change in number reporting problems	+/-xx	+/-xx	+/-xx	+/-xx	+/-xx	+/-xx	+/-xx	+/-xx	+/-xx	+/-xx
% difference in number reporting problems- control-intervention)	+/-xx.x	+/-xx.x	+/-xx.x	+/-xx.x	+/-xx.x	+/-xx.x	+/-xx.x	+/-xx.x	+/-xx.x	+/-xx.x

Table 12: Assessment of missing outcome measures by group

Variable	Intervention Group (n=) (%)			Control Group (n=) (%)		
Timepoint	T1	T2	T3	T1	T2	T3
SF-36						
<i>Physical functioning: Items 3a, 3b, 3c, 3d,3e,3f,3g,3h,3i,3j</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Role-physical: Items 4a,4b,4c,4d</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Bodily pain: Items 7,8</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>General Health: Items 1,11a,11b,11c,11d</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Vitality: Items 9a,9e,9g,9i</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Social functioning: Items 6,10</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Role-emotional: Items 5a,5b,5c</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Mental health: Items 9b,9c,9d,9f,9h</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)

Variable	Intervention Group (n=) (%)			Control Group (n=) (%)		
Timepoint	T1	T2	T3	T1	T2	T3
<i>Reported health transition: Item 2</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
LTC-6	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
UCLA-3	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
Barthel Index	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
EQ-5D-5L						
<i>Mobility (levels1-5)</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Self-care (levels1-5)</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Usual activities (levels1-5)</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Pain/discomfort (levels1-5)</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
<i>Anxiety/depression (levels1-5)</i>	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
EQ-5D-5L VAS	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
Number of deaths	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
Number of hospital admissions	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
Number of hospital readmissions	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)

Variable	Intervention Group (n=) (%)			Control Group (n=) (%)		
Timepoint	T1	T2	T3	T1	T2	T3
Total number of days spent in hospital	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
Number of prescribed medications	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)

Table 13: Harm by Group (Adverse Events)

Adverse event	Intervention Group
AE classification (%)	Xx(xx.x)
AE classification (%)	Xx(xx.x)
AE classification (%)	Xx(xx.x)
AE classification (%)	Xx(xx.x)

Table 14: Harm by Group (Serious Adverse Events)

Serious Adverse event	Intervention Group	Control Group
Death*	Xx(xx.x)	Xx(xx.x)
Life threatening*	Xx(xx.x)	Xx(xx.x)
Hospitalisation*	Xx(xx.x)	Xx(xx.x)
Significant disability or incapacity*	Xx(xx.x)	Xx(xx.x)
Congenital anomaly or birth defect*	Xx(xx.x)	Xx(xx.x)
Considered by the investigator to be an important medical event*	Xx(xx.x)	Xx(xx.x)
Details of SAE		
Details of SAE		
Details of SAE		

*related to the intervention only.

Appendix 14: Case Report Forms

GP CRFs and adverse events CRFs were identical for baseline, three-month follow-up and six month follow-up. Only the baseline CRFs are included to avoid repetition.

CONFIDENTIAL

GP CASE REPORT FORM

BASELINE



**The Holistic Assessment and Care Planning in Partnership
Intervention Study**

Participant Study Number:

Participant Initials:

Sponsor:

Plymouth University

Chief Investigator:

Helen Lyndon

INSTRUCTIONS FOR COMPLETING THE CRF



General instructions

- Write in black ballpoint pen
- Complete all data fields as requested, using a ☒ where appropriate
- Ensure all data boxes are completed accurately
- Do not leave data boxes empty – enter a leading zero if necessary e.g.

Weight

0	7	0
---	---	---

 kg

Participant initials

The participant's initials should be entered as follows

e.g. for Josephine Fiona Brown:

Participant Initials

J	F	B
---	---	---

If the participant does not have a middle name, use a dash between the first and last initials

e.g. for Caroline Kent:

Participant Initials

C	-	K
---	---	---

If the surname is hyphenated, use only the first letter of the first part of the surname

e.g. for Tracey Penelope Smith-Jones:

Participant Initials

T	P	S
---	---	---

If the participant has multiple middle names, only the first middle initial should be used.

Dates

Dates should be entered as follows e.g. for 12th June 2018:

Date

1	2
---	---

 /

0	6
---	---

 /

2	0	1	8
---	---	---	---

If any data are unknown, enter NK for 'not known' e.g. where day is not known:

Date

N	K
---	---

 /

0	6
---	---

 /

2	0	1	8
---	---	---	---

Or where day and month are not known:

Date

N	K
---	---

 /

N	K
---	---

 /

2	0	1	8
---	---	---	---

Correcting data

To make corrections, cross out the error with a SINGLE LINE. DO NOT USE CORRECTING FLUID.

Record the correction next to the original entry, then DATE and INITIAL the change e.g.

Age (years)

6	89
---	---------------

 JB 01.10.18

Yes / No

Where Yes / No response options are given please tick one box only

SCREENINGPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS Date of visit / / **INCLUSION CRITERIA**

Yes No

- | | | |
|--|--------------------------|--------------------------|
| 1. Aged 65 years and over | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Moderately frail (eFI 0.24 - 0.36) or severely frail (eFI > 0.36) | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Frailty confirmed by PRISMA7 instrument | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Able to give informed consent | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Living in own home / supported living accommodation | <input type="checkbox"/> | <input type="checkbox"/> |

If the answer to any of the INCLUSION CRITERIA is NO the participant is NOT eligible for inclusion in the study. Please file this form in the HAPPI Complete Documents folder.

EXCLUSION CRITERIA

Yes No

- | | | |
|--|--------------------------|--------------------------|
| 6. Fit or mildly frail (eFI 0.13 – 0.24) | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Lives in a care home | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Is in receipt of palliative care, on gold standards framework register or where clinician feels they have limited life expectancy | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Lacks mental capacity to give informed consent | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Already on the caseload of a Community Matron | <input type="checkbox"/> | <input type="checkbox"/> |

If the answer to any of the EXCLUSION CRITERIA is YES the participant is NOT eligible for inclusion in the study. Please file this form in the HAPPI Complete Documents folder.

CONSENT

Yes No

If the participant is eligible, written informed consent may now be obtained

Has the participant given consent?

☐

If no, please provide reason

If the participant is unable or unwilling to provide consent, they must not be included in the study. Please file this form in the HAPPI Complete Documents folder.

THE ASSESSOR MUST SIGN BELOW TO CONFIRM THE PARTICIPANT IS ELIGIBLE FOR INCLUSION IN THE HAPPI STUDY

NAME (BLOCK CAPITALS)

Signature

Date

 / /

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **DEMOGRAPHICS**Gender Male ☐ Female ☐Date of birth / / What best describes your current relationship status? **PLEASE TICK ONE BOX ONLY**Single ☐ Divorced or civil partnership dissolved ☐Married or in a civil partnership ☐ Widowed or surviving civil partner ☐Who does the participant live with (if anybody) in their current home? **PLEASE TICK ALL BOXES THAT APPLY**Live alone ☐ Children over 18 ☐Spouse/partner ☐ Other family ☐Parent(s) ☐ Non-family ☐Children under 18 ☐*Now please ask the participant to complete the BASELINE questionnaire*Has the participant questionnaire been completed? Yes ☐ No ☐

If no, please provide reason

Completed by (CAPITALS)

Signature

Date / / **Please now:**

- Log in to the study website and follow the instructions to mark the baseline visit as complete
- Photocopy the SCREENING CRF, BASELINE CRF and BASELINE QUESTIONNAIRE and send the originals to PenCTU in the Freepost envelope provided

CONFIDENTIAL

INTERVENTION CASE REPORT FORM



**The Holistic Assessment and Care Planning in Partnership
Intervention Study**

Participant Study Number:

Participant Initials:

Sponsor:

Plymouth University

Chief Investigator:

Helen Lyndon

INSTRUCTIONS FOR COMPLETING THE CRF



General instructions

- Write in black ballpoint pen
- Complete all data fields as requested, using a ☒ where appropriate
- Ensure all data boxes are completed accurately
- Do not leave data boxes empty – enter a leading zero if necessary e.g.

Weight

0	7	0
---	---	---

 kg

Participant initials

The participant's initials should be entered as follows

e.g. for Josephine Fiona Brown:

Participant Initials

J	F	B
---	---	---

If the participant does not have a middle name, use a dash between the first and last initials

e.g. for Caroline Kent:

Participant Initials

C	-	K
---	---	---

If the surname is hyphenated, use only the first letter of the first part of the surname

e.g. for Tracey Penelope Smith-Jones:

Participant Initials

T	P	S
---	---	---

If the participant has multiple middle names, only the first middle initial should be used.

Dates

Dates should be entered as follows e.g. for 12th June 2018:

Date

1	2
---	---

 /

0	6
---	---

 /

2	0	1	8
---	---	---	---

If any data are unknown, enter NK for 'not known' e.g. where day is not known:

Date

N	K
---	---

 /

0	6
---	---

 /

2	0	1	8
---	---	---	---

Or where day and month are not known:

Date

N	K
---	---

 /

N	K
---	---

 /

2	0	1	8
---	---	---	---

Correcting data

To make corrections, cross out the error with a SINGLE LINE. DO NOT USE CORRECTING FLUID.

Record the correction next to the original entry, then DATE and INITIAL the change e.g.

Age (years)

6	89
---	---------------

 JB 01.10.18

Yes / No

Where Yes / No response options are given please tick one box only

VISIT 1PARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **VISIT DETAILS**

Has the visit been completed?

Yes ☐No ☐If no, reason visit
wasn't completed

If yes, date of visit

 / / **DOCUMENTS USED (Skip this section if the visit wasn't completed)**

Yes

No

1.	Conversation Guide	<input type="checkbox"/>	<input type="checkbox"/>
2.	Gait Speed Test	<input type="checkbox"/>	<input type="checkbox"/>
3.	Clinical Frailty Scale	<input type="checkbox"/>	<input type="checkbox"/>
4.	Multifactorial Risk Assessment Tool (MFRAT)	<input type="checkbox"/>	<input type="checkbox"/>
5.	FRAX tool	<input type="checkbox"/>	<input type="checkbox"/>
6.	Numeric pain scale	<input type="checkbox"/>	<input type="checkbox"/>
7.	Pain assessment record	<input type="checkbox"/>	<input type="checkbox"/>
8.	Abbey Pain Scale (for use in patients with cognitive impairment)	<input type="checkbox"/>	<input type="checkbox"/>
9.	Medication review summary	<input type="checkbox"/>	<input type="checkbox"/>
10.	STOPP-START medication review tool	<input type="checkbox"/>	<input type="checkbox"/>
11.	MUST 5 Step Guidance	<input type="checkbox"/>	<input type="checkbox"/>
12.	MUST Flowchart	<input type="checkbox"/>	<input type="checkbox"/>
13.	MUST Full Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
14.	RCP Bedside Vision Check	<input type="checkbox"/>	<input type="checkbox"/>
15.	Whispered Voice Test	<input type="checkbox"/>	<input type="checkbox"/>
16.	Clinical Checklist for Lower Urinary Tract Symptoms	<input type="checkbox"/>	<input type="checkbox"/>
17.	ICIQ Bladder Diary	<input type="checkbox"/>	<input type="checkbox"/>
18.	Self-Assessment of Your Urinary Problems	<input type="checkbox"/>	<input type="checkbox"/>
19.	Bowel Assessment Form	<input type="checkbox"/>	<input type="checkbox"/>
20.	Clinical Checklist for Faecal Incontinence	<input type="checkbox"/>	<input type="checkbox"/>
21.	BGS CGA and Problem List	<input type="checkbox"/>	<input type="checkbox"/>
22.	CFT Treatment Escalation Plan Booklet	<input type="checkbox"/>	<input type="checkbox"/>
23.	Barthel Index	<input type="checkbox"/>	<input type="checkbox"/>
24.	UCLA 3-Item Loneliness Scale	<input type="checkbox"/>	<input type="checkbox"/>

Please continue to next page

VISIT 1

 PARTICIPANT STUDY NUMBER

 PARTICIPANT INITIALS


DOCUMENTS USED <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
25.	Caregiver Strain Index	<input type="checkbox"/>	<input type="checkbox"/>
26.	CFT Capacity Assessment Policy	<input type="checkbox"/>	<input type="checkbox"/>
27.	CAM Delirium Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
28.	GPCog	<input type="checkbox"/>	<input type="checkbox"/>
29.	Geriatric Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
30.	Hospital Anxiety and Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
31.	CFT Personalised Support Plan Template: Part 1 My Medical Plan	<input type="checkbox"/>	<input type="checkbox"/>
32.	CFT Personalised Support Plan Template: Part 2 My Well-being Plan	<input type="checkbox"/>	<input type="checkbox"/>

REFERRALS MADE <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
1.	General Practitioner	<input type="checkbox"/>	<input type="checkbox"/>
2.	Geriatrician	<input type="checkbox"/>	<input type="checkbox"/>
3.	Physiotherapy	<input type="checkbox"/>	<input type="checkbox"/>
4.	Occupational Therapy	<input type="checkbox"/>	<input type="checkbox"/>
5.	Speech Therapy	<input type="checkbox"/>	<input type="checkbox"/>
6.	Dietician	<input type="checkbox"/>	<input type="checkbox"/>
7.	Intermediate Care	<input type="checkbox"/>	<input type="checkbox"/>
8.	Adult Social Care	<input type="checkbox"/>	<input type="checkbox"/>
9.	Continuing Care	<input type="checkbox"/>	<input type="checkbox"/>
10.	District Nurses	<input type="checkbox"/>	<input type="checkbox"/>
11.	Falls Clinic	<input type="checkbox"/>	<input type="checkbox"/>
12.	Dementia Services	<input type="checkbox"/>	<input type="checkbox"/>
13.	Voluntary Sector	<input type="checkbox"/>	<input type="checkbox"/>
14.	Other, please state	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>			

Completed by (CAPITALS)		<input type="text"/>
Signature	<input type="text"/>	Date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Please now:

- Photocopy the VISIT 1 CRF and send the originals to PenCTU in the Freepost envelope provided

VISIT 2

PARTICIPANT STUDY NUMBER

PARTICIPANT INITIALS



VISIT DETAILS

Has the visit been completed? Yes ☐ No ☐

If no, reason visit wasn't completed

If yes, date of visit / /

DOCUMENTS USED (Skip this section if the visit wasn't completed)

	Yes	No
1. Conversation Guide	<input type="checkbox"/>	<input type="checkbox"/>
2. Gait Speed Test	<input type="checkbox"/>	<input type="checkbox"/>
3. Clinical Frailty Scale	<input type="checkbox"/>	<input type="checkbox"/>
4. Multifactorial Risk Assessment Tool (MFRAT)	<input type="checkbox"/>	<input type="checkbox"/>
5. FRAX tool	<input type="checkbox"/>	<input type="checkbox"/>
6. Numeric pain scale	<input type="checkbox"/>	<input type="checkbox"/>
7. Pain assessment record	<input type="checkbox"/>	<input type="checkbox"/>
8. Abbey Pain Scale (for use in patients with cognitive impairment)	<input type="checkbox"/>	<input type="checkbox"/>
9. Medication review summary	<input type="checkbox"/>	<input type="checkbox"/>
10. STOPP-START medication review tool	<input type="checkbox"/>	<input type="checkbox"/>
11. MUST 5 Step Guidance	<input type="checkbox"/>	<input type="checkbox"/>
12. MUST Flowchart	<input type="checkbox"/>	<input type="checkbox"/>
13. MUST Full Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
14. RCP Bedside Vision Check	<input type="checkbox"/>	<input type="checkbox"/>
15. Whispered Voice Test	<input type="checkbox"/>	<input type="checkbox"/>
16. Clinical Checklist for Lower Urinary Tract Symptoms	<input type="checkbox"/>	<input type="checkbox"/>
17. ICIQ Bladder Diary	<input type="checkbox"/>	<input type="checkbox"/>
18. Self-Assessment of Your Urinary Problems	<input type="checkbox"/>	<input type="checkbox"/>
19. Bowel Assessment Form	<input type="checkbox"/>	<input type="checkbox"/>
20. Clinical Checklist for Faecal Incontinence	<input type="checkbox"/>	<input type="checkbox"/>
21. BGS CGA and Problem List	<input type="checkbox"/>	<input type="checkbox"/>
22. CFT Treatment Escalation Plan Booklet	<input type="checkbox"/>	<input type="checkbox"/>
23. Barthel Index	<input type="checkbox"/>	<input type="checkbox"/>
24. UCLA 3-Item Loneliness Scale	<input type="checkbox"/>	<input type="checkbox"/>

Please continue to next page

VISIT 2

PARTICIPANT STUDY NUMBER

PARTICIPANT INITIALS



DOCUMENTS USED <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
25.	Caregiver Strain Index	<input type="checkbox"/>	<input type="checkbox"/>
26.	CFT Capacity Assessment Policy	<input type="checkbox"/>	<input type="checkbox"/>
27.	CAM Delirium Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
28.	GPCog	<input type="checkbox"/>	<input type="checkbox"/>
29.	Geriatric Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
30.	Hospital Anxiety and Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
31.	CFT Personalised Support Plan Template: Part 1 My Medical Plan	<input type="checkbox"/>	<input type="checkbox"/>
32.	CFT Personalised Support Plan Template: Part 2 My Well-being Plan	<input type="checkbox"/>	<input type="checkbox"/>

REFERRALS MADE <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
1.	General Practitioner	<input type="checkbox"/>	<input type="checkbox"/>
2.	Geriatrician	<input type="checkbox"/>	<input type="checkbox"/>
3.	Physiotherapy	<input type="checkbox"/>	<input type="checkbox"/>
4.	Occupational Therapy	<input type="checkbox"/>	<input type="checkbox"/>
5.	Speech Therapy	<input type="checkbox"/>	<input type="checkbox"/>
6.	Dietician	<input type="checkbox"/>	<input type="checkbox"/>
7.	Intermediate Care	<input type="checkbox"/>	<input type="checkbox"/>
8.	Adult Social Care	<input type="checkbox"/>	<input type="checkbox"/>
9.	Continuing Care	<input type="checkbox"/>	<input type="checkbox"/>
10.	District Nurses	<input type="checkbox"/>	<input type="checkbox"/>
11.	Falls Clinic	<input type="checkbox"/>	<input type="checkbox"/>
12.	Dementia Services	<input type="checkbox"/>	<input type="checkbox"/>
13.	Voluntary Sector	<input type="checkbox"/>	<input type="checkbox"/>
14.	Other, please state	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>			

Completed by (CAPITALS)	<input type="text"/>		
Signature	<input type="text"/>	Date	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Please now:

- Photocopy the VISIT 2 CRF and send the originals to PenCTU in the Freepost envelope provided

VISIT 3

PARTICIPANT STUDY NUMBER

PARTICIPANT INITIALS



VISIT DETAILS

Has the visit been completed? Yes ☐ No ☐

If no, reason visit wasn't completed

If yes, date of visit

 / /

DOCUMENTS USED (Skip this section if the visit wasn't completed)

Yes No

1.	Conversation Guide	<input type="checkbox"/>	<input type="checkbox"/>
2.	Gait Speed Test	<input type="checkbox"/>	<input type="checkbox"/>
3.	Clinical Frailty Scale	<input type="checkbox"/>	<input type="checkbox"/>
4.	Multifactorial Risk Assessment Tool (MFRAT)	<input type="checkbox"/>	<input type="checkbox"/>
5.	FRAX tool	<input type="checkbox"/>	<input type="checkbox"/>
6.	Numeric pain scale	<input type="checkbox"/>	<input type="checkbox"/>
7.	Pain assessment record	<input type="checkbox"/>	<input type="checkbox"/>
8.	Abbey Pain Scale (for use in patients with cognitive impairment)	<input type="checkbox"/>	<input type="checkbox"/>
9.	Medication review summary	<input type="checkbox"/>	<input type="checkbox"/>
10.	STOPP-START medication review tool	<input type="checkbox"/>	<input type="checkbox"/>
11.	MUST 5 Step Guidance	<input type="checkbox"/>	<input type="checkbox"/>
12.	MUST Flowchart	<input type="checkbox"/>	<input type="checkbox"/>
13.	MUST Full Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
14.	RCP Bedside Vision Check	<input type="checkbox"/>	<input type="checkbox"/>
15.	Whispered Voice Test	<input type="checkbox"/>	<input type="checkbox"/>
16.	Clinical Checklist for Lower Urinary Tract Symptoms	<input type="checkbox"/>	<input type="checkbox"/>
17.	ICIQ Bladder Diary	<input type="checkbox"/>	<input type="checkbox"/>
18.	Self-Assessment of Your Urinary Problems	<input type="checkbox"/>	<input type="checkbox"/>
19.	Bowel Assessment Form	<input type="checkbox"/>	<input type="checkbox"/>
20.	Clinical Checklist for Faecal Incontinence	<input type="checkbox"/>	<input type="checkbox"/>
21.	BGS CGA and Problem List	<input type="checkbox"/>	<input type="checkbox"/>
22.	CFT Treatment Escalation Plan Booklet	<input type="checkbox"/>	<input type="checkbox"/>
23.	Barthel Index	<input type="checkbox"/>	<input type="checkbox"/>
24.	UCLA 3-Item Loneliness Scale	<input type="checkbox"/>	<input type="checkbox"/>

Please continue to next page

VISIT 3

 PARTICIPANT STUDY NUMBER

 PARTICIPANT INITIALS


DOCUMENTS USED <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
25.	Caregiver Strain Index	<input type="checkbox"/>	<input type="checkbox"/>
26.	CFT Capacity Assessment Policy	<input type="checkbox"/>	<input type="checkbox"/>
27.	CAM Delirium Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
28.	GPCog	<input type="checkbox"/>	<input type="checkbox"/>
29.	Geriatric Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
30.	Hospital Anxiety and Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
31.	CFT Personalised Support Plan Template: Part 1 My Medical Plan	<input type="checkbox"/>	<input type="checkbox"/>
32.	CFT Personalised Support Plan Template: Part 2 My Well-being Plan	<input type="checkbox"/>	<input type="checkbox"/>

REFERRALS MADE <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
1.	General Practitioner	<input type="checkbox"/>	<input type="checkbox"/>
2.	Geriatrician	<input type="checkbox"/>	<input type="checkbox"/>
3.	Physiotherapy	<input type="checkbox"/>	<input type="checkbox"/>
4.	Occupational Therapy	<input type="checkbox"/>	<input type="checkbox"/>
5.	Speech Therapy	<input type="checkbox"/>	<input type="checkbox"/>
6.	Dietician	<input type="checkbox"/>	<input type="checkbox"/>
7.	Intermediate Care	<input type="checkbox"/>	<input type="checkbox"/>
8.	Adult Social Care	<input type="checkbox"/>	<input type="checkbox"/>
9.	Continuing Care	<input type="checkbox"/>	<input type="checkbox"/>
10.	District Nurses	<input type="checkbox"/>	<input type="checkbox"/>
11.	Falls Clinic	<input type="checkbox"/>	<input type="checkbox"/>
12.	Dementia Services	<input type="checkbox"/>	<input type="checkbox"/>
13.	Voluntary Sector	<input type="checkbox"/>	<input type="checkbox"/>
14.	Other, please state	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>			

Completed by (CAPITALS)	<input type="text"/>		
Signature	<input type="text"/>	Date	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Please now:

- Photocopy the VISIT 3 CRF and send the originals to PenCTU in the Freepost envelope provided

VISIT 4

PARTICIPANT STUDY NUMBER

PARTICIPANT INITIALS



VISIT DETAILS

Has the visit been completed?

Yes

☐

No

☐

If no, reason visit
wasn't completed

If yes, date of visit

 / /

DOCUMENTS USED *(Skip this section if the visit wasn't completed)*

Yes

No

1.	Conversation Guide	<input type="checkbox"/>	<input type="checkbox"/>
2.	Gait Speed Test	<input type="checkbox"/>	<input type="checkbox"/>
3.	Clinical Frailty Scale	<input type="checkbox"/>	<input type="checkbox"/>
4.	Multifactorial Risk Assessment Tool (MFRAT)	<input type="checkbox"/>	<input type="checkbox"/>
5.	FRAX tool	<input type="checkbox"/>	<input type="checkbox"/>
6.	Numeric pain scale	<input type="checkbox"/>	<input type="checkbox"/>
7.	Pain assessment record	<input type="checkbox"/>	<input type="checkbox"/>
8.	Abbey Pain Scale (for use in patients with cognitive impairment)	<input type="checkbox"/>	<input type="checkbox"/>
9.	Medication review summary	<input type="checkbox"/>	<input type="checkbox"/>
10.	STOPP-START medication review tool	<input type="checkbox"/>	<input type="checkbox"/>
11.	MUST 5 Step Guidance	<input type="checkbox"/>	<input type="checkbox"/>
12.	MUST Flowchart	<input type="checkbox"/>	<input type="checkbox"/>
13.	MUST Full Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
14.	RCP Bedside Vision Check	<input type="checkbox"/>	<input type="checkbox"/>
15.	Whispered Voice Test	<input type="checkbox"/>	<input type="checkbox"/>
16.	Clinical Checklist for Lower Urinary Tract Symptoms	<input type="checkbox"/>	<input type="checkbox"/>
17.	ICIQ Bladder Diary	<input type="checkbox"/>	<input type="checkbox"/>
18.	Self-Assessment of Your Urinary Problems	<input type="checkbox"/>	<input type="checkbox"/>
19.	Bowel Assessment Form	<input type="checkbox"/>	<input type="checkbox"/>
20.	Clinical Checklist for Faecal Incontinence	<input type="checkbox"/>	<input type="checkbox"/>
21.	BGS CGA and Problem List	<input type="checkbox"/>	<input type="checkbox"/>
22.	CFT Treatment Escalation Plan Booklet	<input type="checkbox"/>	<input type="checkbox"/>
23.	Barthel Index	<input type="checkbox"/>	<input type="checkbox"/>
24.	UCLA 3-Item Loneliness Scale	<input type="checkbox"/>	<input type="checkbox"/>

Please continue to next page

VISIT 4

 PARTICIPANT STUDY NUMBER

 PARTICIPANT INITIALS


DOCUMENTS USED <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
25.	Caregiver Strain Index	<input type="checkbox"/>	<input type="checkbox"/>
26.	CFT Capacity Assessment Policy	<input type="checkbox"/>	<input type="checkbox"/>
27.	CAM Delirium Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
28.	GPCog	<input type="checkbox"/>	<input type="checkbox"/>
29.	Geriatric Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
30.	Hospital Anxiety and Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
31.	CFT Personalised Support Plan Template: Part 1 My Medical Plan	<input type="checkbox"/>	<input type="checkbox"/>
32.	CFT Personalised Support Plan Template: Part 2 My Well-being Plan	<input type="checkbox"/>	<input type="checkbox"/>

REFERRALS MADE <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
1.	General Practitioner	<input type="checkbox"/>	<input type="checkbox"/>
2.	Geriatrician	<input type="checkbox"/>	<input type="checkbox"/>
3.	Physiotherapy	<input type="checkbox"/>	<input type="checkbox"/>
4.	Occupational Therapy	<input type="checkbox"/>	<input type="checkbox"/>
5.	Speech Therapy	<input type="checkbox"/>	<input type="checkbox"/>
6.	Dietician	<input type="checkbox"/>	<input type="checkbox"/>
7.	Intermediate Care	<input type="checkbox"/>	<input type="checkbox"/>
8.	Adult Social Care	<input type="checkbox"/>	<input type="checkbox"/>
9.	Continuing Care	<input type="checkbox"/>	<input type="checkbox"/>
10.	District Nurses	<input type="checkbox"/>	<input type="checkbox"/>
11.	Falls Clinic	<input type="checkbox"/>	<input type="checkbox"/>
12.	Dementia Services	<input type="checkbox"/>	<input type="checkbox"/>
13.	Voluntary Sector	<input type="checkbox"/>	<input type="checkbox"/>
14.	Other, please state	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>			

Completed by (CAPITALS)	<input type="text"/>
Signature	<input type="text"/>
Date	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Please now:

- Photocopy the VISIT 4 CRF and send the originals to PenCTU in the Freepost envelope provided

VISIT 5

PARTICIPANT STUDY NUMBER

PARTICIPANT INITIALS



VISIT DETAILS

Has the visit been completed?

Yes

☐

No

☐

If no, reason visit
wasn't completed

If yes, date of visit

 / /

DOCUMENTS USED *(Skip this section if the visit wasn't completed)*

Yes

No

1.	Conversation Guide	<input type="checkbox"/>	<input type="checkbox"/>
2.	Gait Speed Test	<input type="checkbox"/>	<input type="checkbox"/>
3.	Clinical Frailty Scale	<input type="checkbox"/>	<input type="checkbox"/>
4.	Multifactorial Risk Assessment Tool (MFRAT)	<input type="checkbox"/>	<input type="checkbox"/>
5.	FRAX tool	<input type="checkbox"/>	<input type="checkbox"/>
6.	Numeric pain scale	<input type="checkbox"/>	<input type="checkbox"/>
7.	Pain assessment record	<input type="checkbox"/>	<input type="checkbox"/>
8.	Abbey Pain Scale (for use in patients with cognitive impairment)	<input type="checkbox"/>	<input type="checkbox"/>
9.	Medication review summary	<input type="checkbox"/>	<input type="checkbox"/>
10.	STOPP-START medication review tool	<input type="checkbox"/>	<input type="checkbox"/>
11.	MUST 5 Step Guidance	<input type="checkbox"/>	<input type="checkbox"/>
12.	MUST Flowchart	<input type="checkbox"/>	<input type="checkbox"/>
13.	MUST Full Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
14.	RCP Bedside Vision Check	<input type="checkbox"/>	<input type="checkbox"/>
15.	Whispered Voice Test	<input type="checkbox"/>	<input type="checkbox"/>
16.	Clinical Checklist for Lower Urinary Tract Symptoms	<input type="checkbox"/>	<input type="checkbox"/>
17.	ICIQ Bladder Diary	<input type="checkbox"/>	<input type="checkbox"/>
18.	Self-Assessment of Your Urinary Problems	<input type="checkbox"/>	<input type="checkbox"/>
19.	Bowel Assessment Form	<input type="checkbox"/>	<input type="checkbox"/>
20.	Clinical Checklist for Faecal Incontinence	<input type="checkbox"/>	<input type="checkbox"/>
21.	BGS CGA and Problem List	<input type="checkbox"/>	<input type="checkbox"/>
22.	CFT Treatment Escalation Plan Booklet	<input type="checkbox"/>	<input type="checkbox"/>
23.	Barthel Index	<input type="checkbox"/>	<input type="checkbox"/>
24.	UCLA 3-Item Loneliness Scale	<input type="checkbox"/>	<input type="checkbox"/>

Please continue to next page

VISIT 5

PARTICIPANT STUDY NUMBER

PARTICIPANT INITIALS



DOCUMENTS USED <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
25.	Caregiver Strain Index	<input type="checkbox"/>	<input type="checkbox"/>
26.	CFT Capacity Assessment Policy	<input type="checkbox"/>	<input type="checkbox"/>
27.	CAM Delirium Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
28.	GPCog	<input type="checkbox"/>	<input type="checkbox"/>
29.	Geriatric Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
30.	Hospital Anxiety and Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
31.	CFT Personalised Support Plan Template: Part 1 My Medical Plan	<input type="checkbox"/>	<input type="checkbox"/>
32.	CFT Personalised Support Plan Template: Part 2 My Well-being Plan	<input type="checkbox"/>	<input type="checkbox"/>

REFERRALS MADE <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
1.	General Practitioner	<input type="checkbox"/>	<input type="checkbox"/>
2.	Geriatrician	<input type="checkbox"/>	<input type="checkbox"/>
3.	Physiotherapy	<input type="checkbox"/>	<input type="checkbox"/>
4.	Occupational Therapy	<input type="checkbox"/>	<input type="checkbox"/>
5.	Speech Therapy	<input type="checkbox"/>	<input type="checkbox"/>
6.	Dietician	<input type="checkbox"/>	<input type="checkbox"/>
7.	Intermediate Care	<input type="checkbox"/>	<input type="checkbox"/>
8.	Adult Social Care	<input type="checkbox"/>	<input type="checkbox"/>
9.	Continuing Care	<input type="checkbox"/>	<input type="checkbox"/>
10.	District Nurses	<input type="checkbox"/>	<input type="checkbox"/>
11.	Falls Clinic	<input type="checkbox"/>	<input type="checkbox"/>
12.	Dementia Services	<input type="checkbox"/>	<input type="checkbox"/>
13.	Voluntary Sector	<input type="checkbox"/>	<input type="checkbox"/>
14.	Other, please state	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>			

Completed by (CAPITALS)	<input type="text"/>		
Signature	<input type="text"/>	Date	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Please now:

- Photocopy the VISIT 5 CRF and send the originals to PenCTU in the Freepost envelope provided

VISIT 6

PARTICIPANT STUDY NUMBER

PARTICIPANT INITIALS



VISIT DETAILS

Has the visit been completed?

Yes ☐

No ☐

If no, reason visit wasn't completed

If yes, date of visit

 / /

DOCUMENTS USED *(Skip this section if the visit wasn't completed)*

Yes

No

1.	Conversation Guide	<input type="checkbox"/>	<input type="checkbox"/>
2.	Gait Speed Test	<input type="checkbox"/>	<input type="checkbox"/>
3.	Clinical Frailty Scale	<input type="checkbox"/>	<input type="checkbox"/>
4.	Multifactorial Risk Assessment Tool (MFRAT)	<input type="checkbox"/>	<input type="checkbox"/>
5.	FRAX tool	<input type="checkbox"/>	<input type="checkbox"/>
6.	Numeric pain scale	<input type="checkbox"/>	<input type="checkbox"/>
7.	Pain assessment record	<input type="checkbox"/>	<input type="checkbox"/>
8.	Abbey Pain Scale (for use in patients with cognitive impairment)	<input type="checkbox"/>	<input type="checkbox"/>
9.	Medication review summary	<input type="checkbox"/>	<input type="checkbox"/>
10.	STOPP-START medication review tool	<input type="checkbox"/>	<input type="checkbox"/>
11.	MUST 5 Step Guidance	<input type="checkbox"/>	<input type="checkbox"/>
12.	MUST Flowchart	<input type="checkbox"/>	<input type="checkbox"/>
13.	MUST Full Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
14.	RCP Bedside Vision Check	<input type="checkbox"/>	<input type="checkbox"/>
15.	Whispered Voice Test	<input type="checkbox"/>	<input type="checkbox"/>
16.	Clinical Checklist for Lower Urinary Tract Symptoms	<input type="checkbox"/>	<input type="checkbox"/>
17.	ICIQ Bladder Diary	<input type="checkbox"/>	<input type="checkbox"/>
18.	Self-Assessment of Your Urinary Problems	<input type="checkbox"/>	<input type="checkbox"/>
19.	Bowel Assessment Form	<input type="checkbox"/>	<input type="checkbox"/>
20.	Clinical Checklist for Faecal Incontinence	<input type="checkbox"/>	<input type="checkbox"/>
21.	BGS CGA and Problem List	<input type="checkbox"/>	<input type="checkbox"/>
22.	CFT Treatment Escalation Plan Booklet	<input type="checkbox"/>	<input type="checkbox"/>
23.	Barthel Index	<input type="checkbox"/>	<input type="checkbox"/>
24.	UCLA 3-Item Loneliness Scale	<input type="checkbox"/>	<input type="checkbox"/>

Please continue to next page

VISIT 6

 PARTICIPANT STUDY NUMBER

 PARTICIPANT INITIALS


DOCUMENTS USED <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
25.	Caregiver Strain Index	<input type="checkbox"/>	<input type="checkbox"/>
26.	CFT Capacity Assessment Policy	<input type="checkbox"/>	<input type="checkbox"/>
27.	CAM Delirium Screening Tool	<input type="checkbox"/>	<input type="checkbox"/>
28.	GPCog	<input type="checkbox"/>	<input type="checkbox"/>
29.	Geriatric Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
30.	Hospital Anxiety and Depression Score	<input type="checkbox"/>	<input type="checkbox"/>
31.	CFT Personalised Support Plan Template: Part 1 My Medical Plan	<input type="checkbox"/>	<input type="checkbox"/>
32.	CFT Personalised Support Plan Template: Part 2 My Well-being Plan	<input type="checkbox"/>	<input type="checkbox"/>

REFERRALS MADE <i>(Skip this section if the visit wasn't completed)</i>		Yes	No
1.	General Practitioner	<input type="checkbox"/>	<input type="checkbox"/>
2.	Geriatrician	<input type="checkbox"/>	<input type="checkbox"/>
3.	Physiotherapy	<input type="checkbox"/>	<input type="checkbox"/>
4.	Occupational Therapy	<input type="checkbox"/>	<input type="checkbox"/>
5.	Speech Therapy	<input type="checkbox"/>	<input type="checkbox"/>
6.	Dietician	<input type="checkbox"/>	<input type="checkbox"/>
7.	Intermediate Care	<input type="checkbox"/>	<input type="checkbox"/>
8.	Adult Social Care	<input type="checkbox"/>	<input type="checkbox"/>
9.	Continuing Care	<input type="checkbox"/>	<input type="checkbox"/>
10.	District Nurses	<input type="checkbox"/>	<input type="checkbox"/>
11.	Falls Clinic	<input type="checkbox"/>	<input type="checkbox"/>
12.	Dementia Services	<input type="checkbox"/>	<input type="checkbox"/>
13.	Voluntary Sector	<input type="checkbox"/>	<input type="checkbox"/>
14.	Other, please state	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/>			

Completed by (CAPITALS)	<input type="text"/>	
Signature	<input type="text"/>	Date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Please now:

- Photocopy the VISIT 6 CRF and send the originals to PenCTU in the Freepost envelope provided

CONFIDENTIAL

GP CASE REPORT FORM

BASELINE



**The Holistic Assessment and Care Planning in Partnership
Intervention Study**

Participant Study Number:

Participant Initials:

Sponsor:

Plymouth University

Chief Investigator:

Helen Lyndon

INSTRUCTIONS FOR COMPLETING THE CRF



General instructions

- Write in black ballpoint pen
- Complete all data fields as requested, using a ☒ where appropriate
- Ensure all data boxes are completed accurately
- Do not leave data boxes empty – enter a leading zero if necessary e.g.

Weight

0	7	0
---	---	---

 kg

Participant initials

The participant's initials should be entered as follows

e.g. for Josephine Fiona Brown:

Participant Initials

J	F	B
---	---	---

If the participant does not have a middle name, use a dash between the first and last initials

e.g. for Caroline Kent:

Participant Initials

C	-	K
---	---	---

If the surname is hyphenated, use only the first letter of the first part of the surname

e.g. for Tracey Penelope Smith-Jones:

Participant Initials

T	P	S
---	---	---

If the participant has multiple middle names, only the first middle initial should be used.

Dates

Dates should be entered as follows e.g. for 12th June 2018:

Date

1	2
---	---

 /

0	6
---	---

 /

2	0	1	8
---	---	---	---

If any data are unknown, enter NK for 'not known' e.g. where day is not known:

Date

N	K
---	---

 /

0	6
---	---

 /

2	0	1	8
---	---	---	---

Or where day and month are not known:

Date

N	K
---	---

 /

N	K
---	---

 /

2	0	1	8
---	---	---	---

Correcting data

To make corrections, cross out the error with a SINGLE LINE. DO NOT USE CORRECTING FLUID.

Record the correction next to the original entry, then DATE and INITIAL the change e.g.

Age (years)

6	89
---	----

 JB 01.10.18

Yes / No

Where Yes / No response options are given please tick one box only

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS Date completed dd / mm / yyyy**eFI**Score **MEDICATIONS**Number of medications prescribed in total **HOSPITAL ADMISSIONS**Number of hospital admissions in the last 3 months Number of hospital readmissions in the last 3 months Total number of days spent in hospital in the last 3 months

Completed by (CAPITALS)

Position held

Signature

Date

dd / mm / yyyy*Please now:*

- Photocopy this CRF and send the originals to PenCTU in the Freepost envelope provided

Or

- Email the completed CRF to: penctudata@plymouth.ac.uk

CONFIDENTIAL

INTERVENTION VISIT
ADVERSE EVENTS



**The Holistic Assessment and Care Planning in Partnership
Intervention Study**

Participant Study Number:

Participant Initials:

Sponsor:

Plymouth University

Chief Investigator:

Helen Lyndon

INTERVENTION VISIT ADVERSE EVENTS

PARTICIPANT INITIALS

PARTICIPANT STUDY NUMBER



Adverse event	Start date	Stop date ^a	Severity ^b (tick one)			In the opinion of the CI was the event related to study intervention? (tick one)					Did the CI consider the event to be serious? ^c		Nurse or CI Initials
	(enter NK in dd, mm and/or yyyy fields if date is uncertain)		Mild	Moderate	Severe	Not related	Unlikely	Possibly	Probably	Definitely	Yes	No	
1	dd/mm/yyyy	dd/mm/yyyy											
2	dd/mm/yyyy	dd/mm/yyyy											
3	dd/mm/yyyy	dd/mm/yyyy											
4	dd/mm/yyyy	dd/mm/yyyy											
5	dd/mm/yyyy	dd/mm/yyyy											
6	dd/mm/yyyy	dd/mm/yyyy											
7	dd/mm/yyyy	dd/mm/yyyy											
8	dd/mm/yyyy	dd/mm/yyyy											
9	dd/mm/yyyy	dd/mm/yyyy											
10	dd/mm/yyyy	dd/mm/yyyy											

a) Stop date: if AE is unresolved at visit, enter ONGOING and record on sheet for next visit for review
b) Severity: **Mild**: An event that is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities
Moderate: An event that is sufficiently discomforting to interfere with normal everyday activities
Severe: An event that prevents normal everyday activities

c) Assessment of seriousness must be based on the definitions in protocol section 15.1
Was the event serious?: If yes, complete an SAE form.

PAGE OF

Once complete, please file a photocopy of this form in the participant's file. Send the original to the PenCTU with the other relevant CRF pages.

CONFIRMATION OF CI OR AUTHORISED DELEGATE'S REVIEW OF THE COMPLETED AE INFORMATION:

DATE: / /

COMPLETED BY (CAPITALS)

SIGNATURE:

CRF Version: FINAL 1.0_08.08.2019

IRAS No. 229210

Appendix 15: Outcome Measures Questionnaire Booklets

Outcome measures questionnaire booklets were identical at baseline, three and six month follow-up, therefore, only the baseline questionnaire is included to avoid repetition.

PARTICIPANT QUESTIONNAIRE BOOKLET

BASELINE



The Holistic Assessment and Care Planning in Partnership Intervention Study

Participant Study Number:

Participant Initials:

Date completed:

 / /

Sponsor:

Plymouth University

Chief Investigator:

Helen Lyndon

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **SF36**

1. In general, would you say your health is?

Excellent <input type="text"/>	Very good <input type="text"/>	Good <input type="text"/>	Fair <input type="text"/>	Poor <input type="text"/>
-----------------------------------	-----------------------------------	------------------------------	------------------------------	------------------------------

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago <input type="text"/>	Somewhat better now than one year ago <input type="text"/>	About the same as one year ago <input type="text"/>	Somewhat worse now than one year ago <input type="text"/>	Much worse now than one year ago <input type="text"/>
--	---	---	--	---

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Circle one number on each line		
	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling or stooping	1	2	3
9. Walking more than a mile	1	2	3
10. Walking several hundred yards	1	2	3
11. Walking one hundred yards	1	2	3
12. Bathing or dressing yourself	1	2	3

Please continue to next page

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **SF36**

During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

	Circle one number on each line				
	All the time	Most of the time	Some of the time	A little of the time	None of the time
13. Cut down on the amount of time you spend on work or other activities	1	2	3	4	5
14. Accomplished less than you would like	1	2	3	4	5
15. Were limited in the kind of work or other activities	1	2	3	4	5
16. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Circle one number on each line				
	All the time	Most of the time	Some of the time	A little of the time	None of the time
17. Cut down on the amount of time you spend on work or other activities	1	2	3	4	5
18. Accomplished less than you would like	1	2	3	4	5
19. Didn't do work or other activities as carefully as usual	1	2	3	4	5

20. During the **past 4 weeks**, to what extent has your **physical health or emotional problems** interfered with your social activities with family, friends, neighbours or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

21. How much **bodily pain** have you had during the **past 4 weeks**?

None	Very mild	Mild	Moderate	Severe	Very severe
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please continue to next page

BASELINE

 PARTICIPANT STUDY NUMBER

 PARTICIPANT INITIALS

SF36

22. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all <input type="text"/>	Slightly <input type="text"/>	Moderately <input type="text"/>	Quite a bit <input type="text"/>	Extremely <input type="text"/>
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These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time **during the past 4 weeks**...

	Circle one number on each line				
	All the time	Most of the time	Some of the time	A little of the time	None of the time
23. did you feel full of pep?	1	2	3	4	5
24. have you been very nervous?	1	2	3	4	5
25. have you felt so down in the dumps nothing could cheer you up?	1	2	3	4	5
26. have you felt calm and peaceful?	1	2	3	4	5
27. did you have a lot of energy?	1	2	3	4	5
28. have you felt downhearted and blue?	1	2	3	4	5
29. did you feel worn out?	1	2	3	4	5
30. have you been a happy person?	1	2	3	4	5
31. did you feel tired?	1	2	3	4	5

32. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time <input type="text"/>	Most of the time <input type="text"/>	Some of the time <input type="text"/>	A little of the time <input type="text"/>	None of the time <input type="text"/>
---	--	--	--	--

Please continue to next page

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **SF36**

How TRUE or FALSE is each of the following statements for you?

	Circle one number on each line				
	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

LTC-6

Thinking about the last 12 months, when you received care and support for your conditions(s)...

1. Did you discuss what was most important to *you* in managing your own health?

Not at all	<input type="checkbox"/>
Rarely	<input type="checkbox"/>
Some of the time	<input type="checkbox"/>
Almost always	<input type="checkbox"/>

2. Were you involved as much as you wanted to be in decisions about your care or treatment?

Not at all	<input type="checkbox"/>
To some extent	<input type="checkbox"/>
More often than not	<input type="checkbox"/>
Almost always	<input type="checkbox"/>

3. How would you describe the amount of information you receive to help you to manage your health?

I didn't receive any information	<input type="checkbox"/>
I rarely received enough information	<input type="checkbox"/>
I sometimes received enough information	<input type="checkbox"/>
I always received enough information	<input type="checkbox"/>

Please continue to next page

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **LTC-6**

Thinking about the last 12 months, when you received care and support for your conditions(s)...

4. Have you had enough support from your health and social team to help you manage your health?

I have had no support	<input type="checkbox"/>
I have not had enough support	<input type="checkbox"/>
I have sometimes felt supported	<input type="checkbox"/>
I have always felt supported	<input type="checkbox"/>

5. Do you think the support and care you receive is joined up and working for you?

Never	<input type="checkbox"/>
Rarely	<input type="checkbox"/>
Sometimes	<input type="checkbox"/>
Always	<input type="checkbox"/>

6. How confident are you that you can manage your own health?

Not at all confident	<input type="checkbox"/>
Not too confident	<input type="checkbox"/>
Somewhat confident	<input type="checkbox"/>
Very confident	<input type="checkbox"/>

UCLA loneliness scale

Please answer the following three questions

	Hardly ever	Some of the time	Often
How often do you feel like you lack companionship?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How often do you feel left out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How often do you feel isolated from others?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please continue to next page

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **BARTHEL INDEX OF ACTIVITIES OF DAILY LIVING**

Choose the box for the statement that most closely corresponds to your current level of ability for each of the following 10 items.

Bowels

Incontinent (or needs to be given enemas)	<input type="checkbox"/>
Occasional accident (once/week)	<input type="checkbox"/>
Continent	<input type="checkbox"/>

Transfer

Unable – no sitting balance	<input type="checkbox"/>
Major help (one or two people, physical), can sit	<input type="checkbox"/>
Minor help (verbal or physical)	<input type="checkbox"/>
Independent	<input type="checkbox"/>

Bladder

Incontinent, or catheterised and unable to manage alone	<input type="checkbox"/>
Occasional accident (max. once per 24 hours)	<input type="checkbox"/>
Continent (for over 7 days)	<input type="checkbox"/>

Mobility

Immobile	<input type="checkbox"/>
Wheelchair independent, including corners etc.	<input type="checkbox"/>
Walks with help of one person (verbal or physical)	<input type="checkbox"/>
Independent (but may use any aid e.g. stick)	<input type="checkbox"/>

Grooming

Needs help with personal care	<input type="checkbox"/>
Independent face/hair/teeth/shaving (implements provided)	<input type="checkbox"/>

Please continue to next page

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **BARTHEL INDEX OF ACTIVITIES OF DAILY LIVING**

Choose the box for the statement that most closely corresponds to your current level of ability for each of the following 10 items.

Dressing

Dependent	<input type="checkbox"/>
Needs help, but can do about half unaided	<input type="checkbox"/>
Independent (including buttons, zips, laces etc.)	<input type="checkbox"/>

Toilet use

Dependent	<input type="checkbox"/>
Needs help, but can do something alone	<input type="checkbox"/>
Independent (on and off, dressing, wiping)	<input type="checkbox"/>

Stairs

Unable	<input type="checkbox"/>
Needs help (verbal, physical, carrying aid)	<input type="checkbox"/>
Independent up and down	<input type="checkbox"/>

Feeding

Unable	<input type="checkbox"/>
Needs help cutting, spreading butter, etc.	<input type="checkbox"/>
Independent (food provided within reach)	<input type="checkbox"/>

Bathing

Dependent	<input type="checkbox"/>
Independent (or in shower)	<input type="checkbox"/>

Please continue to next page

BASELINEPARTICIPANT STUDY NUMBER PARTICIPANT INITIALS **EQ5D**Under each heading, please tick ONE box that best describes your health **TODAY****Mobility**

I have no problems in walking about	<input type="checkbox"/>
I have slight problems in walking about	<input type="checkbox"/>
I have moderate problems in walking about	<input type="checkbox"/>
I have severe problems in walking about	<input type="checkbox"/>
I am unable to walk about	<input type="checkbox"/>

Self-care

I have no problems washing or dressing myself	<input type="checkbox"/>
I have slight problems washing or dressing myself	<input type="checkbox"/>
I have moderate problems washing or dressing myself	<input type="checkbox"/>
I have severe problems washing or dressing myself	<input type="checkbox"/>
I am unable to wash or dress myself	<input type="checkbox"/>

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities	<input type="checkbox"/>
I have slight problems doing my usual activities	<input type="checkbox"/>
I have moderate problems doing my usual activities	<input type="checkbox"/>
I have severe problems doing my usual activities	<input type="checkbox"/>
I am unable to do my usual activities	<input type="checkbox"/>

Pain/Discomfort

I have no pain or discomfort	<input type="checkbox"/>
I have slight pain or discomfort	<input type="checkbox"/>
I have moderate pain or discomfort	<input type="checkbox"/>
I have severe pain or discomfort	<input type="checkbox"/>
I have extreme pain or discomfort	<input type="checkbox"/>

Anxiety/Depression

I am not anxious or depressed	<input type="checkbox"/>
I am slightly anxious or depressed	<input type="checkbox"/>
I am moderately anxious or depressed	<input type="checkbox"/>
I am severely anxious or depressed	<input type="checkbox"/>
I am extremely anxious or depressed	<input type="checkbox"/>

Please continue to next page

BASELINE

PARTICIPANT STUDY NUMBER

PARTICIPANT INITIALS

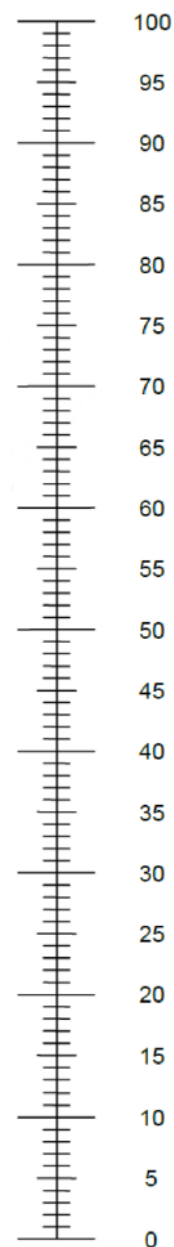


EQ5D

- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY**.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

THANK YOU

Appendix 16: Skewness, kurtosis and z-values all outcome measures

Table 1a: SF-36 (Intervention)

Intervention									
	M00			M03			M06		
Physical functioning									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	0.547	0.427	1.28	0.662	0.448	1.48	0.745	0.456	1.64
Kurtosis	-0.808	0.833	-1.65	0.015	0.872	0.02	-0.620	0.887	-0.70
Role-Physical									
Skewedness	0.11	0.46	0.24	0.02	0.46	0.04	0.29	0.46	0.63
Kurtosis	-1.42	0.90	-1.58	-1.33	0.90	-1.48	-1.38	0.90	-1.53
Bodily Pain									
Skewedness	0.61	0.46	1.35	0.77	0.46	1.69	0.37	0.46	0.81
Kurtosis	-0.25	0.89	-0.28	0.25	0.89	0.28	-0.99	0.89	-1.12
General Health									
Skewedness	0.18	0.47	0.38	0.75	0.47	1.58	0.85	0.47	1.80
Kurtosis	-1.19	0.92	-1.29	-0.28	0.92	-0.31	0.09	0.92	0.09
Vitality									
Skewedness	0.49	0.47	1.03	0.53	0.47	1.13	1.17	0.47	2.48
Kurtosis	-0.58	0.92	-0.63	-0.63	0.92	-0.68	0.48	0.92	0.53
Social Functioning									
Skewedness	-0.40	0.46	-0.88	-0.58	0.46	-1.28	1.24	0.46	2.72
Kurtosis	-1.32	0.89	-1.49	-1.17	0.89	-1.33	6.83	0.89	7.70
Role-Emotional									
Skewedness	-0.56	0.46	-1.24	-1.14	0.46	-2.51	-1.53	0.46	-3.35
Kurtosis	-1.31	0.89	-1.48	0.36	0.89	0.41	1.42	0.89	1.60
Mental Health									
Skewedness	-1.21	0.47	-2.57	-1.00	0.47	-2.11	3.84	0.47	8.13
Kurtosis	1.17	0.92	1.27	0.56	0.92	0.61	17.28	0.92	18.83
Reported Health Transition									
Skewedness	0.13	0.46	0.28	0.43	0.46	0.94	0.65	0.46	1.42
Kurtosis	-0.43	0.89	-0.49	0.16	0.89	0.18	-0.04	0.89	-0.04

Table 1b: SF-36 (Control)

Control									
M00				M03			M06		
Physical functioning									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	0.78	0.46	1.67	0.84	0.47	1.77	1.23	0.48	2.56
Kurtosis	-0.39	0.90	-0.43	0.70	0.92	0.77	1.04	0.93	1.11
Role-Physical									
Skewedness	-0.32	0.48	-0.67	0.21	0.48	0.43	0.14	0.48	0.28
Kurtosis	-1.12	0.93	-1.19	-1.53	0.93	-1.64	-1.54	0.93	-1.65
Bodily Pain									
Skewedness	-0.17	0.48	-0.36	-0.10	0.48	-0.20	0.24	0.48	0.51
Kurtosis	-1.23	0.93	-1.32	-1.74	0.93	-1.87	-1.48	0.93	-1.59
General Health									
Skewedness	0.18	0.50	0.36	0.66	0.50	1.32	0.14	0.50	0.28
Kurtosis	-0.63	0.97	-0.65	-1.08	0.97	-1.12	-0.77	0.97	-0.79
Vitality									
Skewedness	-0.09	0.48	-0.18	0.35	0.48	0.72	0.45	0.48	0.94
Kurtosis	0.26	0.93	0.28	-0.81	0.93	-0.87	-0.50	0.93	-0.53
Social Functioning									
Skewedness	-0.57	0.48	-1.18	-0.59	0.48	-1.22	-1.32	0.48	-2.74
Kurtosis	-0.55	0.93	-0.59	-0.28	0.93	-0.30	1.18	0.93	1.26
Role-Emotional									
Skewedness	-0.90	0.48	-1.87	-0.93	0.48	-1.94	-1.33	0.48	-2.76
Kurtosis	-0.67	0.93	-0.72	-0.73	0.93	-0.79	0.73	0.93	0.78
Mental Health									
Skewedness	-0.62	0.49	-1.27	-2.18	0.49	-4.43	-0.83	0.49	-1.69
Kurtosis	-0.83	0.95	-0.87	7.27	0.95	7.63	0.46	0.95	0.48
Reported Health Transition									
Skewedness	0.78	0.48	1.63	0.36	0.48	0.75	0.22	0.48	0.45
Kurtosis	1.14	0.93	1.22	0.22	0.93	0.23	-1.18	0.93	-1.26

Table 2: LTC-6 (intervention and control)

Intervention									
	M00			M03			M06		
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	0.04	0.47	0.09	-0.65	0.47	-1.37	-0.22	0.47	-0.46
Kurtosis	-1.00	0.92	-1.09	-0.57	0.92	-0.63	-0.90	0.92	-0.98
Control									
	M00			M03			M06		
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	-0.72	0.48	-1.50	-0.75	0.48	-1.55	-0.98	0.48	-2.03
Kurtosis	-0.02	0.93	-0.02	-0.94	0.93	-1.00	0.59	0.93	0.64

Table 3: UCLA-3 (intervention and control)

Intervention									
	M00			M03			M06		
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	1.19	0.46	2.61	1.17	0.46	2.56	1.17	0.46	2.56
Kurtosis	0.30	0.89	0.34	-0.12	0.89	-0.13	-0.12	0.89	-0.13
Control									
	M00			M03			M06		
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	1.53	0.48	3.18	0.88	0.48	1.83	0.88	0.48	1.83
Kurtosis	1.78	0.93	1.90	-0.78	0.93	-0.83	-0.78	0.93	-0.83

Table 4: Barthel Index (intervention and control)

Intervention									
	M00			M03			M06		
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	-1.42	0.48	-2.95	-1.74	0.48	-3.62	-1.17	0.48	-2.44
Kurtosis	0.95	0.93	1.02	2.75	0.93	2.95	0.15	0.93	0.16
Control									
	M00			M03			M06		
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	-1.25	0.49	-2.54	-2.22	0.49	-4.53	-1.71	0.49	-3.48
Kurtosis	0.40	0.95	0.42	4.46	0.95	4.68	1.94	0.95	2.03

Table 5: EQ-5D-5L (intervention and control)

Intervention									
	M00			M03			M06		
EQ-5D-5L Index Values									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	-1.05	0.46	-2.26	-1.49	0.46	-3.22	-0.67	0.46	-1.44
Kurtosis	2.05	0.90	2.28	3.32	0.90	3.68	1.10	0.90	1.22
	M00			M03			M06		
EQ-5D-5L VAS									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	-0.54	0.46	-1.16	-0.93	0.46	-2.00	-0.48	0.46	-1.04
Kurtosis	-0.33	0.90	-0.37	1.12	0.90	1.24	0.01	0.90	0.02
Control									
	M00			M03			M06		
EQ-5D-5L Index Values									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	-1.20	0.49	-2.44	-1.11	0.49	-2.27	-0.20	0.49	-0.40
Kurtosis	0.95	0.95	0.99	0.94	0.95	0.98	-0.02	0.95	-0.02
	M00			M03			M06		
EQ-5D-5L VAS									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	0.44	0.49	0.89	-0.76	0.49	-1.55	-0.83	0.49	-1.69
Kurtosis	-0.71	0.95	-0.75	0.81	0.95	0.85	1.60	0.95	1.68

Table 6: Site-reported outcome measures (intervention and control)

Intervention									
Number of hospital admissions									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	3.37	0.46	7.40	3.37	0.46	7.40	2.04	0.46	4.47
Kurtosis	10.16	0.89	11.46	10.16	0.89	11.46	2.33	0.89	2.63
	M00			M03			M06		
Number of hospital re-admissions									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	0.0	0.0	0.0	0.0	0.0	0.0	5.10	0.46	11.19
Kurtosis	0.0	0.0	0.0	0.0	0.0	0.0	26.00	0.89	29.33
Total number of days spent in hospital									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	3.373	0.456	7.404602	4.442	0.456	9.749767	2.941	0.456	6.455479
Kurtosis	10.156	0.887	11.45646	20.482	0.887	23.10381	8.327	0.887	9.392804
Number of prescribed medications									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	1.30	0.46	2.84	0.66	0.46	1.45	0.86	0.46	1.88
Kurtosis	1.33	0.89	1.50	-0.53	0.89	-0.60	0.61	0.89	0.69
Control									
Number of hospital admissions									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	2.28	0.49	4.64	2.39	0.49	4.88	2.19	0.49	4.47
Kurtosis	3.50	0.95	3.67	5.46	0.95	5.73	4.78	0.95	5.02
	M00			M03			M06		
Number of hospital re-admissions									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	0.0	0.0	0.0	0.0	0.0	0.0	3.06	0.49	6.23
Kurtosis	0.0	0.0	0.0	0.0	0.0	0.0	8.09	0.95	8.49
Total number of days spent in hospital									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	3.059	0.491	6.229968	2.394	0.491	4.876507	2.590	0.491	5.274347
Kurtosis	8.085	0.953	8.485696	5.459	0.953	5.729893	6.055	0.953	6.35461
Number of prescribed medications									
	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value	Statistic	Std. Error	z-value
Skewedness	0.02	0.49	0.04	2.31	0.49	4.70	0.20	0.49	0.40
Kurtosis	-0.90	0.95	-0.95	6.80	0.95	7.13	-0.48	0.95	-0.50

Appendix 17: HAPPI Interview Topic Guides



Interview Guide

HAPPI Study - Interviews with trial participants

Interview guide

Protocol title	The Holistic Assessment and care Planning in Partnership Intervention Study (HAPPI)
Protocol version	10
IRAS number	229210
Chief Investigator	Helen Lyndon

Study participant number	
Initials	
Setting	
Interview date	

DEMOGRAPHICS	
Alias:	
Age:	



INTERVIEW GUIDE

PREPARE INTERVIEW

Preparations

- ☐ Introduce yourself with name and position
- ☐ Try to relax the participant for the interview. Is the temperature of the room OK? Would they like a glass of water? How has their week been? What hobbies or activities have they been doing?
- ☐ Make sure the interview is in a quiet place
- ☐ Ask others, not belonging to the interview, if they would kindly leave the room

Introduction

- ☐ Thank the participant for participating
- ☐ Explain the project in brief
- ☐ Explain the aim of the interview

Why is this information being collected?

- a) To make the further trial better
 - b) To identify what didn't go well and therefore has introduced some form of bias into the trial i.e. problems with delivery of the HAPPI intervention or patient's experiences of it
- ☐ Explain the recording device that you are using
 - ☐ Explain what will be done with the data
 - Anonymity and use of an alias, thus we cannot trace back any persons
 - The findings will be published
 - ☐ Explain the interview time will take approximately 20-40 minutes
 - ☐ Ask if all information is clear and if there are any questions before starting the interview

Test the recording device (voice recorder)

HAPPI Interview guide Participant v1.0 17/07/2018
IRAS 229210



1. THE INTERVIEW (where possible using open ended questions)

- a) I would like to explore your overall experiences of the HAPPI trial.
- b) Can you tell me about your participation in the HAPPI trial – how was it for you?

Suggested prompt questions

- *Can you tell me a bit more about xxxxxx that you just mentioned?*
 - *How has it been for you to take part in the HAPPI trial?*
 - *What went well? What did you enjoy? What didn't go so well?*
 - *What benefits or problems have you experienced?*
- c) Did you mind being randomised into either the intervention or the control group?

Suggested prompt questions

- *Why is that so?*
 - *What do you mean by....?*
- d) How did you find completing the questionnaires?
- e) How did you find the trial visits – when the Research Assistants visited to complete your baseline and follow-up measures?

2. For intervention participants only:

- a) I would now like to talk to you about the process that you went through in participating in the HAPPI intervention
- b) Can you tell me about your experiences of receiving the intervention (the nurse visiting you and completing the assessment and care plan with you)?
- c) What did you like about the HAPPI assessment and care planning process?
- d) What can be improved in the HAPPI assessment and care planning process? What difficulties did you encounter? In what way did we meet, or fall short of, your expectations?

3. Overall

- a) In your opinion, is there anything you would change about the HAPPI trial?
- b) Is there anything else that you would like to share with us?



END OF INTERVIEW

- ☐ Stop the recorder
- ☐ Ask the participants whether I may contact them in case of questions regarding the interview for further clarification of some of the points made?
- ☐ Provide the participant of contact details of project team (Helen Lyndon 07919891065 or email helen.lyndon@plymouth.ac.uk)
- ☐ Thank the participant for participating

NOTES (your personal researchers' field notes)



Interview Guide

HAPPI Study - Interviews with nurses

Protocol title	The Holistic Assessment and care Planning in Partnership Study
IRAS number	229210
Chief Investigator	Helen Lyndon

Study participant number	<input type="text"/> <input type="text"/>
Initials	
Setting	
Interview date	

DEMOGRAPHICS	
Alias:	
Age:	



INTERVIEW GUIDE

PREPARE INTERVIEW

Preparations

- ☐ Introduce yourself with name and position
- ☐ Try to relax the nurse for the interview
- ☐ Make sure the interview is in a quiet place

Introduction

- ☐ Thank the nurse for participating
- ☐ Explain the project in brief
- ☐ Explain the aim of the interview
- ☐ Explain the recording device that you are using
- ☐ Explain what will be done with the data
 - o Anonymity and use of an alias, thus we cannot trace back any persons
 - o The findings will be published
- ☐ Explain the interview time will take approximately 20-40 minutes
- ☐ Ask if all information is clear and if there are any questions before starting the interview

Test the recording device (voice recorder)



1. THE INTERVIEW

I would like to explore your overall experiences of the HAPPI trial.

- a) Tell me about your experiences of the HAPPI trial so far.
- b) What did you like about the training session?
- c) What could have been added to the training session?
- d) What did you think about the conversation guide and assessment pack?

2. I would like to talk to you now about the process for identifying patients who were moderately or severely frail to participate in the study.

- a) Did you agree with the classification of the patients into moderately or severely frail? Did the classification seem accurate after assessment?
- b) What are your views on using the eFI to identify patients for further assessment and care planning?

3. I would like to talk to you now about the process that you go through for delivering the HAPPI assessment and care planning intervention

- a) Can you tell me about your experiences of delivering the HAPPI assessment and care planning intervention?
- b) Did you experience any challenges in delivering the HAPPI assessment and care planning intervention? If yes, what were they?
- c) How could we overcome these challenges in future?
- d) Were there any missing components of the assessment and care planning intervention?
- e) What could be improved in the assessment and care planning intervention for the future?
- f) Do you think the HAPPI intervention improved the patient's experience of care received in comparison to normal care? If yes, in what way?

4. I'm interested in exploring your views on the HAPPI trial procedures and design

- a) Can you tell me your thoughts on the different trial components (contacting patients to book assessment visits, using the conversation guide and assessment pack, recording data).

Prompt questions

What difficulties have you encountered?

What have been the positive aspects?



5. Overall

- a) In your opinion, is there anything you would change about the HAPPI trial?
- b) Is there anything further you would like to share with us about delivering the assessment and care planning intervention and the HAPPI trial?
- c) What is your view on rolling HAPPI out into a large scale trial?

END OF INTERVIEW

- ☐ Stop the recorder
- ☐ May I contact you in case I have questions regarding the interview for further clarification of some of the points made?
- ☐ In case you would like to contact the project team or see a copy of the transcript, you can always contact;

Helen Lyndon on 07919891065 or email helen.lyndon@plymouth.ac.uk

- ☐ Thank the participant for participating

NOTES (your personal researchers' field notes)



Interview Guide

HAPPI Study - Interviews with practice administrators

Protocol title	The Holistic Assessment and care Planning in Partnership Study
IRAS number	229210
Chief Investigator	Helen Lyndon

Study participant number	<input type="text"/> <input type="text"/>
Initials	
Setting	
Interview date	

DEMOGRAPHICS	
Alias:	
Age:	



INTERVIEW GUIDE

PREPARE INTERVIEW

Preparations

- ☐ Introduce yourself with name and position
- ☐ Try to relax the person for the interview
- ☐ Make sure the interview is in a quiet place

Introduction

- ☐ Thank the person for participating
- ☐ Explain the project in brief
- ☐ Explain the aim of the interview
- ☐ Explain the recording device that you are using
- ☐ Explain what will be done with the data
 - Anonymity and use of an alias, thus we cannot trace back any persons
 - The findings will be published
- ☐ Explain the interview time will take approximately 20-40 minutes
- ☐ Ask if all information is clear and if there are any questions before starting the interview

Test the recording device (voice recorder)



1. THE INTERVIEW

I would like to explore your overall experiences of identifying patients for the HAPPI trial.

- a) Tell me about your experiences of the HAPPI trial so far.
- b) How long did it take you to complete the tasks relating to the trial i.e:
 - Running the eFI, applying eligibility criteria
 - Sending a recruitment letter to the potential participants
 - Receiving and processing replies.
 - Making the telephone calls if reply was not received within fourteen days
 - Asking the PRISMA7 questions to those phoned
 - Sending the details of the 10 potential participants to the Chief Investigator(CI)
 - Completing email proforma report on 3 and 6 month outcome measures from general practice records system
- c) Do you feel you the time allocated was enough to complete the tasks?

Prompt questions

What difficulties have you encountered?

What have been the positive aspects?

END OF INTERVIEW

- ☐ Stop the recorder
- ☐ May I contact you in case I have questions regarding the interview for further clarification of some of the points made?
- ☐ In case you would like to contact the project team or see a copy of the transcript, you can always contact;

Helen Lyndon on 07919891065 or email helen.lyndon@plymouth.ac.uk

- ☐ Thank the participant for participating

NOTES (your personal researchers' field notes)



Interview Guide

HAPPI Study - Interviews with carers of trial participants

Interview guide

Protocol title	The Holistic Assessment and care Planning in Partnership Intervention Study (HAPPI)
Protocol version	10
IRAS number	229210
Chief Investigator	Helen Lyndon

Study participant number	
Initials	
Setting	
Interview date	

DEMOGRAPHICS	
Alias:	
Age:	



INTERVIEW GUIDE

PREPARE INTERVIEW

Preparations

- ☐ Introduce yourself with name and position
- ☐ Try to relax the participant for the interview. Is the temperature of the room OK? Would they like a glass of water? How has their week been? What hobbies or activities have they been doing?
- ☐ Make sure the interview is in a quiet place
- ☐ Ask others, not belonging to the interview, if they would kindly leave the room

Introduction

- ☐ Thank the participant for participating
- ☐ Explain the project in brief
- ☐ Explain the aim of the interview

Why is this information being collected?

- a) To make the further trial better
- b) To identify what didn't go well and therefore has introduced some form of bias into the trial i.e. problems with delivery of the HAPPI intervention or patient's experiences of it
- ☐ Explain the recording device that you are using
- ☐ Explain what will be done with the data
 - Anonymity and use of an alias, thus we cannot trace back any persons
 - The findings will be published
- ☐ Explain the interview time will take approximately 20-40 minutes
- ☐ Ask if all information is clear and if there are any questions before starting the interview

Test the recording device (voice recorder)

HAPPI Interview guide Participant v1.0 17/07/2018
IRAS 229210



1. THE INTERVIEW (where possible using open ended questions)

- a) I would like to explore your overall experiences of the HAPPI trial.
- b) Can you tell me about your experience of **(Participant's name)** participation in the HAPPI trial – how was it for you?
- c) In your opinion, what were the benefits and drawbacks from **(Participant's name)** participation in the trial?
- d) What were the benefits and drawbacks for you as a carer from **(Participant's name)** participating in the trial?

Suggested prompt questions

- *Can you tell me a bit more about xxxxxx that you just mentioned?*
- *What went well? What did you enjoy? What didn't go so well?*
- *What benefits or problems have you experienced?*

Suggested prompt questions

- *Why is that so?*
- *What do you mean by....?*

2. For intervention participants only:

- a) I would now like to talk to you about the process that **(Participant's name)** went through in participating in the HAPPI intervention
- b) What did you like about the HAPPI assessment and care planning process?
- c) What can be improved in the HAPPI assessment and care planning process? What difficulties did you encounter as a carer with the process? In what way did we meet, or fall short of, your expectations?

3. Overall

- a) In your opinion, is there anything you would change about the HAPPI trial?
- b) Is there anything else that you would like to share with us?



END OF INTERVIEW

- ☐ Stop the recorder

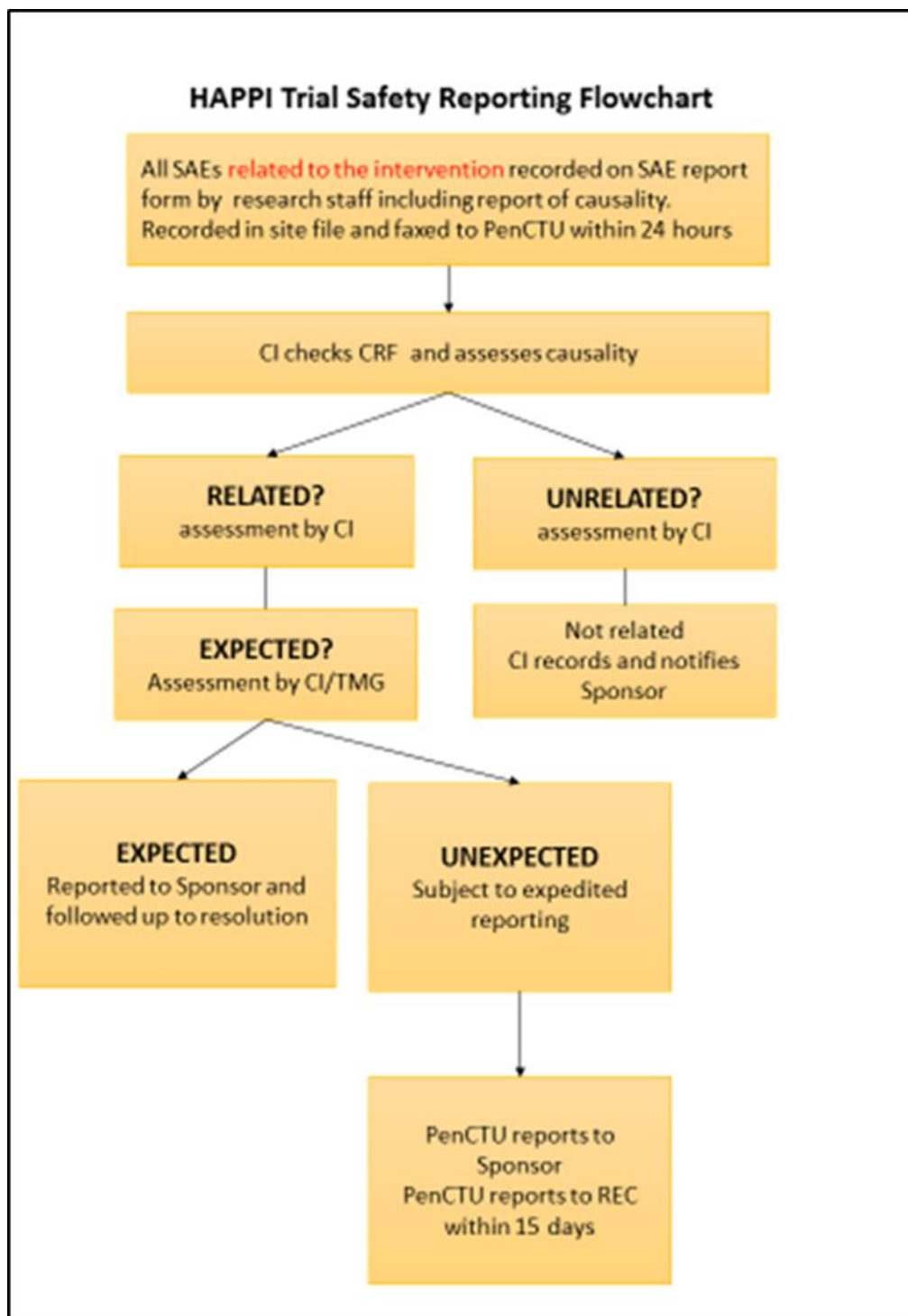
- ☐ Ask the participants whether I may contact them in case of questions regarding the interview for further clarification of some of the points made?

- ☐ Provide the participant of contact details of project team (Helen Lyndon 07919891065 or email helen.lyndon@plymouth.ac.uk)

- ☐ Thank the participant for participating

NOTES (your personal researchers' field notes)

Appendix 18: HAPPI Safety Flow Chart



Appendix 19: NHS REC Approval



**Health Research
Authority**

London - Camberwell St Giles Research Ethics Committee

Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207104 8204

Please note: This is the
favourable opinion of the
REC only and does not allow
you to start your study at NHS
sites in England until you
receive HRA Approval

16 October 2018

Mrs Helen Lyndon
Room S09, Knowledge Spa
Royal Cornwall Hospital
Truro, Cornwall
TR13HD

Dear Mrs Lyndon

Study title:	The Holistic Assessment and care Planning in Partnership Intervention (HAPPI) Study: A cluster randomised, controlled feasibility study of a nurse-led, holistic assessment and care planning intervention for older people living with frailty in primary care.
REC reference:	18/LO/1354
IRAS project ID:	229210

Thank you for your letter of 25th September 2018, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC at a meeting held on 16th October 2018. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

The committee did not approve this research project for the purposes of the Mental Capacity Act 2005. The research may not be carried out on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Covering Letter]		06 June 2018
Covering letter on headed paper [Covering Letter]		19 September 2018
Covering letter on headed paper [Covering Letter]		25 September 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Plymouth University Indemnity Insurance Certificate]		19 July 2018
GP/consultant information sheets or letters [General Practitioner Letter]	V1	17 July 2018
Interview schedules or topic guides for participants [Interview Guide Nurses]	V1	17 July 2018
Interview schedules or topic guides for participants [Interview Guide Study Participants]	V1	17 July 2018
Interview schedules or topic guides for participants [Interview Guide Carers]	V1	17 July 2018
Interview schedules or topic guides for participants [Interview Guide Practice Administrators]	V1	17 July 2018
IRAS Application Form [IRAS_Form_11072018]		11 July 2018
IRAS Application Form XML file [IRAS_Form_11072018]		11 July 2018
IRAS Checklist XML [Checklist_03102018]		03 October 2018
Letter from funder [Letter of confirmation, funder]		19 January 2017

Letter from sponsor [Letter of confirmation, sponsor]		06 July 2018
Letters of invitation to participant [Participant Recruitment Letter] Clean	V2	18 September 2018
Letters of invitation to participant [Participant Recruitment Letter] Tracked Changes	V2	11 September 2018
Participant consent form [Participant Interviews Consent Form]	V1	06 June 2018
Participant consent form [Carers Interviews Consent Form]	V1	06 June 2018
Participant consent form [Clinician/Practice Admin Interviews Consent Form]	V1	17 July 2018
Participant consent form [Consultee Declaration Form]	V1	17 July 2018
Participant consent form [Feasibility Trial Consent Form] Tracked Changes	V2	11 September 2018
Participant consent form [Feasibility Trial Consent Form] Clean	V2	11 September 2018
Participant information sheet (PIS) [PIS Participant Interviews]	V1	17 July 2018
Participant information sheet (PIS) [PIS Consultee]	V1	17 July 2018
Participant information sheet (PIS) [PIS Regaining Capacity]	V1	17 July 2018
Participant information sheet (PIS) [PIS Feasibility Trial Participants] Clean	V2	18 September 2018
Participant information sheet (PIS) [PIS Feasibility Trial Participants] Tracked Changes	V2	11 September 2018
Participant information sheet (PIS) [PIS Carer Interviews]	V2	18 September 2018
Participant information sheet (PIS) [PIS Clinician/Practice Administrator Interviews]	V2	11 September 2018
Referee's report or other scientific critique report [Feedback from successful NIHR CDRF Funding Application]		01 July 2016
Research protocol or project proposal [HAPPI Trial Protocol]	1.0	17 July 2018
Research protocol or project proposal [Trial Protocol Draft V2 19.09.2018 Tracked Changes]	2.0	19 October 2018
Summary CV for Chief Investigator (CI) [CV Helen Lyndon]		17 July 2018
Summary CV for supervisor (student research) [CV Bridie Kent]		01 February 2017
Summary CV for supervisor (student research) [CV Jos latour]		01 October 2017
Summary CV for supervisor (student research) [CV Jon Marsden]		20 February 2018

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators

- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

<http://www.hra.nhs.uk/hra-training/>

18/LO/1354

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Pp 

REC Manager

Mr John Richardson
Chair

Email: nrescommittee.london-camberwellstgiles@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

*Copy to: Professor Jonathan Marsden
Mr Michael Visick, Royal Cornwall Hospitals Trust*

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